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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 54 and 79

[Docket No. APHIS-2007-0127]

RIN 0579-AC92

Scrapie in Sheep and Goats

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the scrapie regulations by changing the risk groups and categories established for individual animals and for flocks, increasing the use of genetic testing as a means of assigning risk levels to animals, reducing movement restrictions for animals found to be genetically less susceptible or resistant to scrapie, and simplifying, reducing, or removing certain recordkeeping requirements. We are also providing designated scrapie epidemiologists with more alternatives and flexibility when testing animals in order to determine flock designations under the regulations. We are changing the definition of high-risk animal, which will change the types of animals eligible for indemnity, and to pay higher indemnity for certain pregnant ewes and does and early maturing ewes and does. The changes will also make the identification and recordkeeping requirements for goat owners consistent with those for sheep owners. These changes affect sheep and goat producers, persons who handle sheep and goats in interstate commerce, and State governments.

DATES: Effective [Insert date 30 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Dr. Diane Sutton, National Scrapie Program Coordinator, Sheep, Goat, Cervid & Equine Health Center, Strategy and Policy, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737-1235; (301) 851-3509.

SUPPLEMENTARY INFORMATION:

Background

Scrapie is a degenerative and eventually fatal disease affecting the central nervous systems of sheep and goats. Scrapie belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). In addition to scrapie, TSEs include, among other diseases, bovine spongiform encephalopathy (BSE) in cattle, chronic wasting disease in deer and elk, and variant Creutzfeldt-Jakob disease in humans. Control of scrapie is complicated because the disease has an extremely long incubation period without clinical signs of the disease.

To control the spread of scrapie within the United States, the Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), administers regulations at 9 CFR part 79, which restrict the interstate movement of certain sheep and goats. APHIS also has regulations at 9 CFR part 54, which describe a voluntary scrapie-free flock certification program.

On September 10, 2015, we published in the *Federal Register* (80 FR 54660-54692, Docket No. APHIS-2007-0127) a proposal¹ to amend the regulations in parts 54 and 79 by changing the requirements for records needed to trace animals, and by adding provisions to link official individual animal identification applied by persons other than the flock owner to the flock of origin in the National Scrapie Database rather than just the person who applied the official identification. The current regulations address tracing exposed animals moved from a

¹ To view the proposed rule, supporting documents, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2007-0127>.

flock to another flock primarily in § 54.8(f) (regarding the responsibility of flock owners to disclose records to APHIS representatives or State representatives for the purpose of tracing animals), in § 79.2(b) (regarding the responsibility of persons applying eartags to maintain appropriate records that permit traceback of animals to the flock in which they originated), and in § 79.6(a)(5) (regarding State responsibilities to do epidemiologic investigations of source and infected flocks that include tracing animals). The changes we proposed would ensure that better records are available for tracing animals by adding requirements in new § 54.8(b), “Records for flocks under a flock plan or PEMMP,” § 79.2(f), “Records required of persons who purchase, acquire, sell, or dispose of animals,” and § 79.2(g), “Records required of persons who apply official identification to animals.”

We also proposed to reduce some recordkeeping, primarily by eliminating the requirement in many cases to read and record individual identification that was applied before a new owner or shipper receives the animal. Further, by making the regulations easier to understand we hope to eliminate cases where owners and markets unnecessarily keep records or apply unneeded identification, or fail to do so, when required through lack of understanding. Also, in cases where genetic testing allows us to determine that all exposed animals in a flock are genetically resistant, use of genetic testing would allow some flocks to avoid being placed under a flock plan or post-exposure management and monitoring plan (PEMMP), thus avoiding the substantial recordkeeping requirements of § 54.8.

We solicited comments concerning our proposal for 60 days ending November 9, 2015. We reopened and extended the deadline for comments until December 9, 2015, in a document published in the *Federal Register* on November 16, 2015 (80 FR 70718, Docket No. APHIS-2007-0127). We received 59 comments by that date. The comments were from private citizens,

sheep and goat breeders, operators of livestock markets, a foreign government, and industry associations. Two commenters supported the rule as proposed. Four commenters were generally opposed to the proposed rule but did not address any specific provisions. The remaining commenters raised a number of concerns related to the proposed rule and program standards. Those concerns are discussed below.

Definitions

One commenter asked us to clarify the definition of *exposed animal*, which appears in both §§ 54.1 and 79.1. The commenter stated that the phrase “or in an enclosure off the premises of the flock” is particularly confusing.

We agree with the commenter and have amended the definition to specify that an *exposed animal* is any animal or embryo that:

- Has been in a flock with a scrapie-positive female animal;
- Has been in an enclosure with a scrapie-positive female animal at any location;
- Resides in a noncompliant flock; or
- Has resided on the premises of a flock before or while it was designated an infected or source flock and before a flock plan was completed.

One commenter recommended the definition of *exposed animal* be revised to clarify that “a date 2 years before the birth of the oldest scrapie-positive animal(s)” means “a date 2 years before the birth of the oldest scrapie-positive animal(s) born in that flock.” We agree and have made the requested change.

One commenter stated that the flock identification number could be issued in a State database and then recorded in the National Scrapie Database. The commenter recommended amending the definition of *flock identification number* to reflect this.

We agree with the commenter and will amend the definition in § 79.1 to read “recorded in” instead of “issued through.”

One commenter stated that the definition of *genetically less susceptible exposed sheep* was unclear. Specifically, the commenter stated that currently most sheep are only genotyped at codon 171, so starting the definition with the words “An exposed sheep or sheep embryo of genotype AA QR” does not make sense. The commenter also asked why AA was used in the definition since most sheep are only genotyped at codon 171 and what “where Q represents any genotype other than R at codon 171” means and what it relates to.

AA QR is used in the definition because exposed sheep that are epidemiologically linked to a positive animal that has valine at codon 136 are tested at codon 136 and AV QR sheep may be treated differently than AA QR sheep when this occurs. All positive sheep are tested at a minimum for codon 171 and 136. The statement “where Q represents any genotype other than R at codon 171” means that sheep that have H, K or any other amino acid other than R will be treated the same as sheep that are Q at codon 171.

We do agree that the definition could be more clearly written, however, and are changing the definition in §§ 54.1 and 79.1 to define a *genetically less susceptible exposed sheep* as any sheep or sheep embryo that is:

- An exposed sheep or sheep embryo of genotype AA QR, unless the Administrator determines that it is epidemiologically linked to a scrapie-positive RR or AA QR sheep or to a scrapie type to which AA QR sheep are not less susceptible; or
- An exposed sheep or sheep embryo of genotype AV QR, unless the Administrator determines that it is epidemiologically linked to a scrapie-positive RR or QR sheep, to a flock that the Administrator has determined may be affected by valine-associated scrapie

(based on an evaluation of the genotypes of the scrapie-positive animals linked to the flock), or to another scrapie type to which AV QR sheep are not less susceptible; or

- An exposed sheep or sheep embryo of a genotype that has been exposed to a scrapie type to which the Administrator has determined that genotype is less susceptible. In this definition R refers to codon 171 and A refers to codon 136, and Q represents any genotype other than R at codon 171 and V represents any genotype other than A at codon 136.

One commenter stated that the definition of *genetically susceptible animal* was unclear and that the phrase “or sheep or sheep embryo of undetermined genotype where Q represents any genotype other than R at codon 171” does not make sense.

We agree that this can be more clearly written and are amending the definition in §§ 54.1 and 79.1 to read “*Genetically susceptible animal*. Any goat or goat embryo, sheep or sheep embryo of a genotype other than RR or QR, where Q represents any genotype other than R at codon 171 or a sheep or sheep embryo of undetermined genotype.”

One commenter asked what is meant by “under continuous inspection” in the definition for *slaughter channels*.

Continuous inspection means an inspector examines each animal before slaughter (antemortem inspection) and the carcass and parts after slaughter (postmortem inspection). For clarity we are amending the definition to specify that official slaughter establishments are under Food Safety and Inspection Service (FSIS) jurisdiction per the Federal Meat Inspection Act or under State inspection that FSIS has recognized as at least equal to Federal inspection or to a custom exempt slaughter establishment as defined by FSIS (9 CFR 303.1) for immediate slaughter, or to an individual for immediate slaughter for personal use or to a terminal feedlot.

One commenter asked if a definition for *tamper-resistant sampling kit* needed to be included in part 79 as well as part 54.

The term *tamper-resistant sampling kit* is used only in part 54. Since it is not used in part 79, it does not need to be defined in that part.

We have made minor changes to other definitions. Specifically, we have amended the definition of *destroyed* in § 54.1 to remove the portion of the definition that allowed for animals to be moved to quarantine facilities because we do not use the word in that sense in the regulations. We note that § 54.7(a)(3) provides for the movement of scrapie-positive and suspect animals for which indemnification is sought to an approved research facility.

We have amended the definition of *flock identification (ID) number* in § 79.1 to specify that APHIS may assign Tribal codes to any federally recognized Tribe that maintains sheep or goats on Tribal lands. We made this change to be consistent with the provisions of a final rule published in the *Federal Register* on January 9, 2013 (78 FR 2040, Docket No. APHIS-2009-0091) that established official identification and documentation requirements for the traceability of livestock moving interstate.

We have amended the definition of *genetically resistant sheep* to specify that the sheep or sheep embryo is of genotype RR at codon 171. We made this change because we had not specified the codon in the proposed rule. We have also amended the definition of *official identification device or method* to refer to § 79.2(a)(2), since that is where the requirements for sheep and goat identification are found.

We have also amended the definition of *slaughter channels* in § 79.1 to remove provisions regarding the sale of animals in slaughter channels. Those provisions now appear in

§ 79.3(g). We have also amended the definition of *slaughter channels* in § 54.1 to be consistent with the changes in § 79.1.

In addition, we have made nonsubstantive editorial changes to the definitions of *high-risk animal* and *owner/hauler statement* to improve clarity.

Non-classical Scrapie

One commenter recommended that any reference to genetic resistance and susceptibility to scrapie, especially in the definitions, should prominently specify that the relationship between genotype and scrapie pertains to classical scrapie and not non-classical scrapie.

APHIS disagrees. While it is true that genetic susceptibility is different for classical and non-classical scrapie, the current language addresses this by including the words "or to a scrapie type to which the sheep are susceptible." Leaving the text as currently written allows maximum flexibility in addressing all types of scrapie. We are making no changes in response to this comment.

One commenter recommended continuing monitoring of animals exposed to non-classical scrapie because non-classical scrapie has been shown to be transmitted through oral inoculation and has a peripheral distribution of infectivity despite the absence of the scrapie prion protein.

APHIS agrees that continued monitoring of animals exposed to non-classical scrapie is warranted. We intend to continue monitoring animals exposed to non-classical scrapie by requiring that they be officially identified with official identification devices or methods assigned to the flock of origin in the National Scrapie Database.

Four commenters recommended that APHIS continue to require identification of Nor98-like scrapie-exposed animals, and flockmates and offspring of these animals, for a period of 5 years after the positive animal left the flock.

APHIS agrees that animals that are in Nor98-like scrapie infected and source flocks and animals originating from these flocks should be identified for a period of 5 years, and the flocks monitored through reporting and testing of clinical suspects and mature animals that die. We note that we have provided for this in the program standards in *Part VIII: Flock Cleanup Plans and PEMMPs*, so there is no need to make changes to the program standards in response to this comment.

Official Identification

Several commenters expressed concern that the rule would prohibit the use of registry tattoos as official identification. This is not the case. The rule, through the accompanying program standards, does allow the use of registry tattoos as official identification when the sheep or goat is legibly tattooed and accompanied by a copy of their registration certificate in the name of the current owner or a copy of a completed application for transfer of ownership dated within 60 days of the change in ownership or when accompanied by an interstate certificate of veterinary inspection that lists the flocks of origin and birth, the registry, and the registry tattoo.

Two commenters asked that we confirm that registration/recording tattoos will continue to be allowed for animals in exhibition, educational events, in registry sales, private treaty transfer, and other movements not in slaughter channels or auction markets.

Yes, these animals may move with registry tattoos as currently allowed. The only change is that the registry prefix must be recorded in the premises record for the flock in the National Scrapie Database and documentation of this must accompany the animal, or the registry

organization must be approved based on their ability and willingness to assist APHIS in tracing animals during a disease investigation.

One commenter asked, that for tattoo prefixes containing letters that are prohibited, that the prefix be linked in the National Scrapie Database with the flock identification.

APHIS notes that this rule allows, and the program standards encourage, the cross referencing of flock identification numbers with registry prefixes. No change is being made in response to this comment.

Several commenters expressed concern about how the identification requirements would apply to certain goat breeds. One commenter expressed concern that tail tags would cause unnecessary medical issues for small-eared or earless breeds of goats, such as La Mancha goats.

The rule states that the requirements for use of official identification devices will be maintained on the APHIS website. These requirements are posted on the website as part of the Scrapie Program Standards. There are no approved tags for application to the tail, and the application of an official eartag to any tissue other than the ear is specifically prohibited in the Scrapie Program Standards. APHIS provides for tail fold tattoos, Electronic Implantable Devices (EIDs), and neck collars as acceptable means of identification for very small-eared or earless goats.

One commenter expressed the concern that neck collars may pose a strangulation risk.

APHIS notes that neck collars are commonly used for dairy goats. We believe that, given this usage, the risk of strangulation is likely minimal or neck collars would not be in general use. Further, because the expectation of durability is the same as for eartags, using collars that will break before causing strangulation is allowed and considered desirable. Also, as we explain

below, we are amending the program standards to allow the use of back tags for earless animals moving directly to slaughter as an alternative to using a neck collar.

One commenter requested that earless goats be exempted from the ID requirements.

We recognize that using tail fold tattoos, EIDs, or neck collars for earless goats may present some challenges for breeders; however, using these devices will result in being able to trace a higher percentage of the animals. Not using them will reduce the traceability of these animals. We agree that allowing the use of back tags for earless animals moving direct to slaughter is an acceptable option and are amending the program standards to reflect this.

One commenter stated that eartags are too big for miniature goat breeds and that tattoos should be allowed.

As we explained above, the use of registry tattoos and flock identification tattoos as official identification will be allowed. We also note that very small official eartags are available for use on miniature breeds.

Some commenters stated that we should not require a specific ear to be used for the eartag. One commenter recommended that the right ear forward edge be used for metal tags. Several other commenters recommended that APHIS standardize the placement of eartags in wool sheep to the left ear half way between base and tip of ear and in the middle between the ridges towards the lower edge. The commenters also stated that metal tags should be avoided in wool or fiber animals to minimize the risk of injury to shearers or damage to shearing equipment.

The rule does not require that a specific ear be used for the eartag. We agree that placement on the lower edge of the left ear is preferred for wool or fiber animals and will provide this guidance in the program standards. However, we will not make it a requirement because it

would be overly burdensome to producers given the minimal improvement in traceability that would likely result.

One commenter asked that epidemiological evidence be independently compiled by an entity such as the Occupational Safety and Health Administration (OSHA) regarding the relative safety risk to shearers in flocks using metal vs. plastic tags.

OSHA makes information about planned and accident-related inspections, searchable by Standard Industrial Classification (SIC) codes, available on its website. There are only 17 incidents reported from all causes related to sheep and goat farms (SIC code 0214) in the last 5 years.² Given this small number of incidents, we do not believe there is sufficient data provided to OSHA on shearing injuries for a meaningful comparison. We will include a question on eartag-related shearing problems in the next sheep National Animal Health Monitoring System (NAHMS) study, which we anticipate doing in Fiscal Year 2022. The prior NAHMS was conducted under OMB control number 0579-0188.

One commenter recommended use of a uniform tag color to assist regulatory personnel to quickly and efficiently identify officially tagged sheep and goats.

We agree that a uniform official tag color would be beneficial in rapidly identifying official eartags. However, we also believe that there is a significant benefit for producers to have access to multiple tag colors for purposes of sorting their animals by age, sex, or other characteristics, so we will continue to allow the use of various colors of eartags. APHIS changed the color of metal tags provided by APHIS in 2018 to orange to make them more visible.

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[https://www.osha.gov/pls/imis/industry.search?p_logger=1&sic=0214&naics=&State=All&office_type=All&Office=All&endmonth=01&endday=01&endyear=2011&startmonth=12&startday=31&startyear=2015&owner=&scope=&FedAgnCode=.](https://www.osha.gov/pls/imis/industry.search?p_logger=1&sic=0214&naics=&State=All&office_type=All&Office=All&endmonth=01&endday=01&endyear=2011&startmonth=12&startday=31&startyear=2015&owner=&scope=&FedAgnCode=)

Two commenters asked that the program standards be revised to require all sheep and goats at exhibitions be tagged, regardless of whether they come from in or out of State, as an exhibition is a concentration or commingling point.

For practical purposes, sexually intact sheep and goats of any age and wethers 18 months of age and older that are exhibited are required to be officially identified. There is an exclusion, which would rarely apply, for animals that have never been in interstate commerce and that have not resided on a premises where animals that have been in interstate commerce have been received or from which animals are moved in interstate commerce, where the animals being moved for exhibition are not owned by a person who engages in the interstate commerce of animals, that are moved to exhibitions that are conducted at premises where the interstate commerce of animals does not occur, and where none of the animals exhibited has been in interstate commerce. We believe that this exclusion is required since if such an exhibit were to occur it would fall within the State's authority. We are revising the Scrapie Program Standards to clarify this.

One commenter opposed requiring identification for all sheep because it would be costly not only to producers, but also to auction markets and the veterinary personnel working at markets. Other commenters also opposed requiring identification for goats because of the additional costs.

We are aware that there are costs associated with the application of official identification for both producers and markets. However, the use of official identification is essential for the eradication of scrapie. To achieve scrapie-free status, we must be able to trace mature animals in order to conduct effective slaughter surveillance. Eradication is the goal because achieving scrapie-free status in the United States would significantly enhance trade opportunities and help

to stabilize prices for sheep and goats and their products. Since the goal of the program is eradication and not just control of scrapie, maintaining a low prevalence in goats is not an option.

Three commenters raised concerns regarding the safety of applying ear tags to range goats, particularly mature bucks that have horns. The commenters stated that these goats are wild animals, and that applying ear tags to them presents a risk to both the animals and the people applying the ear tags.

We agree that certain goats may pose a hazard to those applying ear tags if appropriate equipment is not available to restrain the animals. The provisions in § 79.3(a)(2) allow these goats to move in single source groups to slaughter without official individual identification including through markets. This is one option for handling these goats. We will also revise the program standards to allow such goats to move direct to slaughter with official back tags as less restraint is required to apply back tags. We are also amending § 79.3(k) to allow compliance agreements or market agreements to include alternative methods for maintaining traceability or achieving acceptable surveillance levels when the Administrator and the State Animal Health Official agree that the application of an allowed official identification device or method is unsuitable for a specific circumstance. Further, we have amended the definition of *group/lot identification number (GIN)* in § 79.1 to provide that a group lot comprised of animals from a single flock of origin may be subdivided after leaving the premises on which the group lot was formed by adding an S followed by a sequential number to the end of the GIN to create a GIN for each sub group. This will provide additional flexibility in handling unidentified animals moving to slaughter as a single source lot.

Three commenters stated that veterinarians should be able to order and use official scrapie tags for use in regulatory testing, interstate certificates of veterinary inspection (ICVI), or

any other reason requiring official identification. The commenters also stated that APHIS should maintain this traceability information in a user- friendly database. The commenters also stated that county 4- H sheep and goat offices should be assigned official scrapie tags.

In § 79.2(b) of the proposed rule, we proposed to continue to allow State Animal Health Officials and APHIS personnel responsible for States to issue sets of unique serial numbers or flock identification/production numbers for use on official individual identification devices or methods (such as eartags or tattoos). In § 79.2(b)(2), we also proposed to continue to allow the official responsible for issuing eartags in a State to assign serial numbers of official eartags to other responsible persons, such as 4-H leaders, if the State Animal Health Official and APHIS personnel responsible for the State involved agree that such assignments will improve scrapie control and eradication within the State. Distribution of tags is currently managed in the scrapie program utility of the Animal Identification Management System and in certain cases redistributed in the Surveillance Collaboration Services Scrapie (SCS SCR) system. APHIS intends to continue to work to improve the user experience with these systems.

One commenter sought clarification regarding whether the proposed rule would require individual animal identification numbers to be read more than once at approved livestock facilities.

This requires that eartags be read only when an ICVI is required for movement of the animals from the market in cases where flock identification tags were not used to identify the animals or the flock identification of the animals is unknown and the tags must be read to determine the flock of origin. If flock identification tags are present, the flock identification may be listed instead of the individual tag numbers. In the case of animals that arrive at a market on

an ICVI, when allowed by the States involved, the original document may be attached to the new ICVI if the animal IDs of any animals not included in the shipment are struck off the old ICVI.

Recordkeeping

Several commenters had concerns regarding the recordkeeping associated with goat sales and our ability to trace goats based on these requirements.

This rule makes the identification requirements for goats in interstate commerce similar to those currently in place for sheep. The requirements for sheep have been in place since 2002 and have resulted in 82 percent of positive sheep being traced and a 98 percent decrease in the prevalence of scrapie-positive adult sheep slaughtered adjusted for face color.³ We are confident that these requirements will be similarly successful with goats.

Several commenters asked that APHIS provide templates with required fields marked for owner/hauler statements and for any other required information or data as in the case of entities that acquire or dispose of animals.

We agree that such templates would be useful and will post templates on the APHIS Scrapie Program website when they have been approved.

Two commenters opposed the requirement to submit eartagging records to APHIS. Several other commenters indicated that the requirement to submit tagging records could be burdensome if not implemented prudently following successful piloting, and that an option should be provided for electronic storage of required documents in an APHIS system rather than requiring the market to store the records long-term. One commenter stated that the regulations should clearly state that maintaining physical copies of these records at the market for 5 years also meets this requirement.

³ Historically, prevalence rates of scrapie varied by face color and our prevalence estimate is appropriately weighted to match the face color distribution within the U.S. sheep population.

We agree with the commenters and have amended § 79.2(b)(3) to indicate that submission is required only when requested by APHIS. This will allow APHIS to work through issues that may negatively impact stakeholders in small pilots and to implement the requirement through the program standards when the process has been tested and the technology allows for efficient compliance. APHIS will also consider the feasibility of providing electronic document storage. With this change maintaining physical copies of these records at the market for 5 years meets the requirement unless the records are requested.

Some commenters recommended using an owner/hauler statement and lot/group identification for lots of sheep or goats moving directly to slaughter without official ID.

APHIS notes that § 79.3(a)(2) allows single source lots of cull sheep or goats to move unidentified direct to slaughter using an owner/hauler statement without official ID so no changes are being made in response to this comment. We will amend the program standards to improve clarity.

One commenter requested that we allow unidentified animals in interstate commerce that do not cross State lines to move unidentified to markets that are not approved markets.

APHIS notes that as currently written, the regulations allow unidentified animals to move to unapproved in-State markets for sale, provided that the markets tag the animals once they arrive. However, if the person selling the animal through an unapproved in-State market engages in the interstate commerce of animals, they must identify the animals before loading them at their premises. In response to the comment, we are amending § 79.2(a)(1)(iv) to allow producers not already allowed to move animals unidentified to unapproved in-State markets under the regulations to do so if the animals' owner provides tags assigned to his or her flock for the market to apply. As an alternative, such markets may request approval under § 71.20.

We are also amending § 79.2(a)(1)(iv) to add “or the owner of the animal” after “the owner of the premises” since it would be inequitable to apply a different standard to people who rent as opposed to own the premises on which their animals reside.

In § 79.2(a)(1), we had proposed to remove paragraph (vi) because the newly amended paragraph (iv) included animals moved across a State line. However, from questions received during the comment period it became apparent that the removal of this paragraph reduced clarity. Therefore, we will not be removing paragraph (vi). We have made nonsubstantive, editorial changes to the paragraph to update and simplify its language.

One commenter indicated support for the opportunity for markets to enter into agreements with USDA to receive unidentified animals that cannot be traced to their flock of birth or origin if they place a slaughter only tag on them and sell them through slaughter channels, but did not support the reporting requirement for non-compliant shipments. The commenter stated that this requirement asks markets to act against the interests of their customers.

APHIS recognizes that this presents a conflict for markets. Markets may either decline to handle non-compliant shipments or report such shipments to USDA as part of a compliance agreement. No change is being made in response to this comment.

Interstate Certificates of Veterinary Inspection

One commenter recommended that each copy of an ICVI be signed by the issuing veterinarian.

We agree with the commenter and are amending § 79.5(a)(4) to specify that the ICVI must be signed by the issuing State, Federal, Tribal or accredited veterinarian and the signature must be legible on each copy of the ICVI.

One commenter asked us to clarify the flock identification exception in § 79.5(a)(2). The commenter specifically asked what animals could move with flock identification that is assigned to the flock of origin and to explain how “flock of origin tags” differ from tags issued to flock owners with individual flock identification numbers.

We amended that paragraph to refer to “official identification devices or methods that include the flock identification number assigned to the flock of origin in the National Scrapie Database and an individual animal number unique within the flock,” to clarify the requirements.

One commenter asked for clarification of the requirement to record official genotype tests on an ICVI. Another commenter recommended eliminating the requirement to record official genotyping tests on an ICVI in § 79.5(a)(3) as the value of doing so is small and would be impractical to enforce.

We agree with the second commenter that recording official genotype test information on the ICVI is not needed and have removed the requirement.

Surveillance

One commenter stated that the proposed rule does not encourage slaughter surveillance and expressed concern that focus on achieving State sampling minimums will adversely impact slaughter surveillance efforts.

We agree that sampling animals at slaughter is critical and needs to be maintained. This work is currently being done almost entirely by APHIS and its contractors. This final rule requires Consistent States to assist APHIS in sampling in slaughter establishments that are under State inspection or that do not engage in interstate commerce and to meet sampling minimums for animals originating in their State. It is critical to get adequate sampling from all areas of the United States to minimize the risk that cases will go undetected. Further, should the State

sampling minimums adversely impact overall surveillance, APHIS has the ability under the rule to reduce the minimums. For these reasons no change is being made in response to the comment.

Three commenters stated that APHIS should help States ensure their Consistent State status by promoting Regulatory Scrapie Slaughter Surveillance (RSSS) for interstate testing, especially for those States not able to do adequate surveillance testing. The commenters also stated that APHIS should work with State officials to reach out to producers and enlist producer support to alert producers when surveillance levels are not meeting expected levels to retain Consistent State status. The commenters further stated that APHIS or State employees should actively select and test older goats in poor condition for RSSS.

APHIS is committed to working with States to exceed State sampling minimums, and we have prioritized RSSS collections. Goats in a thin or wasted condition are among those targeted for collection.

One commenter recommended that the breed of exposed animals be considered in deciding whether an animal is designated as a high-risk animal.

There is insufficient evidence to demonstrate that any breed of sheep or goat is resistant to scrapie; therefore, no change is being made in response to this comment.

One commenter expressed concern that when APHIS lists a breed as having had a case of scrapie, the animal may not be purebred despite being registered, and that this could have a negative impact on the breed.

APHIS does rely on registry records to determine the breed of an animal and this may result in animals with incorrect pedigrees being considered purebred. The science is not sufficiently mature to reliably and cost-effectively determine the breed of a sheep based on

genotype. We note, however, that the breed of a sheep does not affect the regulatory requirements in any way.

One commenter recommended excluding rare breeds that have been historically free of scrapie from being considered high-risk if they are scrapie exposed. The commenter referenced the work of H.B. Parry⁴ in support of this recommendation.

APHIS notes that rare breeds are by definition few in number. Therefore, they would not be frequently tested for scrapie and would appear to be “historically free” as a result; however, this appearance could be misleading because of the small sample size.

Parry’s work did not include the genotypes of the sheep involved and it is unclear if his observations were a widespread breed trait separate from the genotype at codons 171 and 136 or the result of the genotype at these codons. Further, Parry’s work was done in the United Kingdom where the predominant scrapie type is valine dependent, strains to which AA QQ sheep are resistant. As a result, his work may not be relevant to the United States where the predominant scrapie type is valine independent, strains to which AA QQ sheep are susceptible. As the commenter noted, three breeds considered resistant by Parry have contracted scrapie in the United States. We are making no change in response to this comment as there is adequate flexibility through the pilot project provision and the low-risk exposed animal definition to allow such sheep to be exempted if there is sufficient scientific evidence available to warrant an exemption.

One commenter raised the concern that selecting for genes associated with resistance may be adversely impacting the sheep industry and may be encouraging crossbreeding to add resistance genes to breeds in which they are rare.

⁴ “Elimination of natural scrapie in sheep by sire genotype selection,” *Nature* 277 (1979): 127-129, and *Scrapie Disease in Sheep* (London: Academic Press, 1983).

Several scientific articles have indicated that there is little, if any, difference in production traits between QQ, QR and RR sheep.⁵ One article indicated that there is an association between QQ at codon 171 and the ability to mobilize fat reserves in Scottish Blackface sheep.⁶ Another study showed that within one flock there was a higher litter size in QQ Suffolks than in QR or RR Suffolks but no difference in pounds of lamb weaned.⁷ In the same study, no difference was shown for Columbia, Hampshire, Rambouillet, or western white face sheep. Also, a study showed that as in selecting for any trait, selecting for scrapie resistance may delay progress on other traits, particularly in breeds where R at codon 171 is rare.⁸ APHIS only requires genetic selection in exposed flocks and other higher risk flocks as part of PEMMPs. Further, breeders wishing to retain Q genes can do so with little impact on genetic resistance to scrapie by breeding RR ewes to QR rams and QR ewes to RR rams. Regarding unacknowledged cross breeding, this has occurred on other occasions when a breed is believed to

⁵ “Evaluation of associations between prion haplotypes and growth, carcass, and meat quality traits in a Dorset × Romanov sheep population”, *Journal of Animal Science* 84 (2013): 783-788; “Influence of Prion Protein Genotypes on Milk Production Traits in Spanish Churra Sheep”, *Journal of Dairy Science* 89 (2006): 1784-1791; “Investigation of farmer regard for scrapie-susceptible sheep”, *The Veterinary Record* 158 (2006): 732-734; “Associations between genotypes at codon 171 and 136 of the prion protein gene and production traits in market lambs”, *American Journal of Veterinary Research* 68 (2007): 1073-1078; “Is there a relationship between prion protein genotype and ovulation rate and litter size in sheep?”, *Animal Reproduction Science* 101(2007): 153-157; “Analysis of prion protein genotypes in relation to reproduction traits in local and cosmopolitan German sheep breeds”, *Animal Reproduction Science* 103 (2008): 69-77; “Scrapie resistance and production traits in Rambouillet rams: Ram performance test 2002-2006”, *Research in Veterinary Science* 85 (2008): 345-348; and “Characterization of the PRNP gene locus in Chios dairy sheep and its association with milk production and reproduction traits”, *Animal Genetics* 42 (2011): 406-414.

⁶ “Association of the prion protein gene with individual tissue weights in Scottish Blackface sheep”, *Journal of Animal Science* 86 (2008): 1737-1746.

⁷ “The incidence of genotypes at codon 171 of the prion protein gene (PRNP) in five breeds of sheep and production traits of ewes associated with those genotypes” *Journal of Animal Science* 83 (2005): 455-459.

⁸ “Predicting the consequences of selecting on PrP genotypes on PrP frequencies, performance and inbreeding in commercial meat sheep populations”, *Genet. Sel. Evol.* 39 (2007): 711-729.

be lacking a desirable trait and will occur anytime there are unscrupulous breeders and a financial incentive. We are not making any changes to the regulations based on this comment.

The commenter stated that, in the case of 400 dairy sheep seized and euthanized in 2000-2001, none tested positive for scrapie. The commenter therefore requested that we provide the history, by year, of the number of positives, breed and percentage of individuals of infected/source flocks that were positive after laboratory testing.

APHIS notes that in the case of the dairy sheep, the disease of concern was not scrapie but BSE. The information requested by the commenter is provided in the charts in the document titled “Scrapie Case Information By Breed, Face Color or Type and or Sampling Stream FY 1999 to 2015” that accompanies this final rule. Copies of the document are available on the Regulations.gov website (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

One commenter agreed with genetic testing to determine risk level and also that AA QR (GLS) & AA RR (GR) should be exempt from destruction and noted that Canada does not exempt AV QR. The commenter stated that male animals are lower risk for transmitting scrapie but are at equal risk of becoming infected and noted that the World Organization for Animal Health does not differentiate male and female animals in their guidelines.

No changes are being made in response to this comment. We believe that there is sufficient flexibility in the definitions for high-risk animals, the genetically susceptible exposed animals, and low risk exposed animals for the Administrator to address any issues that may arise with exposed male animals and exposed AV QR sheep.

One commenter stated that for rare breeds APHIS should consider KK at codon 171 the same as QR for determining scrapie susceptibility.

Unpublished work by USDA Agricultural Research Service has shown that KK171 Barbado sheep are susceptible to scrapie by intracerebral inoculation. A complimentary study using an oronasal route showed that at 70 months post inoculation and at 5 years post inoculation there was no evidence of scrapie in these KK171 sheep. This indicates that KK171 sheep are likely less susceptible to classical scrapie. This rule will give the Administrator the flexibility to address KK171 sheep and any other genotypes in sheep or goats that may prove to be less susceptible or resistant to classical scrapie through the *low-risk animal* definition, the *genetically less-susceptible animal* definition, or through a pilot project once there is sufficient scientific evidence to support such action.

In § 79.4, paragraph (c) provides for testing of scrapie-positive animals, high-risk animals, exposed animals, suspect animals, exposed flocks, infected flocks, noncompliant flocks, and source flocks, and paragraph (c)(1) provides for actions that may be taken if a flock owner fails to make animals available for testing. One commenter stated that in § 79.4(c)(1) the statement “or as mutually agreed” was unclear.

We agree that this statement could be clearer. We are changing “or as mutually agreed” to “or as mutually agreed in writing by the Administrator and the owner,” to clarify the conditions under which an owner could be considered in violation.

Markets and Tagging

Seven commenters supported allowing markets to continue to apply white serial tags issued to them to potential breeding sheep and goats. Six commenters stated that markets should be limited to applying only owner-provided official eartags or blue slaughter-only serial eartags provided by the markets in order to reduce the number of untraceable animals. One commenter opposed these suggestions to limit tagging by markets to slaughter-only tags. That commenter

was concerned that markets would have regulatory action taken against them if a blue tagged animal went back to the farm despite being sold for slaughter only. The commenter stated that many smaller-scale sheep and goat producers have limited marketing opportunities and often rely on livestock markets to sell their animals. The commenter stated further that for some of these markets, the profit margin is so small they offer this more as a public service than a business opportunity. Any additional burden on these markets may result in them no longer accepting sheep and goats. The commenter stated that as long as required records are utilized it should be left up to the individual markets whether they will accept unidentified animals, whether they will apply owner-supplied identification, or whether they choose to apply serial or slaughter-only eartags.

The same commenter supported continuing to allow livestock markets to receive official tags directly from animal health officials and apply these tags to sheep and goats coming into the market untagged.

APHIS believes that while on-farm tagging is ideal, there is a certain percentage of producers who will not choose to do this, whether their reasoning be based on difficulty of tagging, privacy, or other reasons. The model in this rule addresses this concern by allowing these animals to be identified by the market and for records to be kept regarding their movement. Additionally, this model provides a reasonable expectation that the movements will be able to be tracked because the option only applies to sheep and goats direct from a farm. Commingled lots would already have to be identified prior to arriving at the market as is called for in § 79.2(a)(1)(i). In response to these comments we are amending the regulations to allow the State Animal Health Official or the Administrator to limit the assignment of official identification devices or numbers to persons or classes of persons for use on animals that did not

originate in a breeding flock owned by them to slaughter-only devices or numbers. This will give the States flexibility to improve traceability, and also give the Administrator the ability to establish a nationwide policy on official eartag distribution should such State programs prove to be successful in increasing traceability.

One commenter expressed concern that some owners and haulers will not abide by the requirement for owner/hauler statements and asked how animals received without an owner/hauler statement should be handled by markets.

Since either an owner or a hauler may complete the statement, the owner or hauler could complete the owner/hauler statement once they arrive at the market. At markets where owners or haulers do not have the required information to complete the statement, the market may either refuse such animals or the market may enter into a compliance agreement as described in § 79.3(k). To clarify the requirements, we have amended § 79.3(k) as follows: “APHIS may enter into compliance agreements with persons such as dealers and owners of slaughter establishments and markets whereby animals may be received unidentified or without a required owner/hauler statement even if they cannot be identified to their flock of birth or origin because they were moved or commingled while unidentified, in violation of this part or a State requirement as provided by § 79.6.”

One commenter requested that APHIS allow use of other documents that contain the information required on the owner/hauler statement.

The current definition of an owner/hauler statement allows for the use of other documents if they contain the same information as the owner/hauler statement. However, we have amended the definition to clarify that this is intended.

One commenter asked that the animals which would qualify to move for purposes other than slaughter be allowed to be tagged after sale, so that only those animals that are moving for purposes other than slaughter at under 18 months of age would need to be eartagged.

In response to this comment, we are amending §§ 79.2(a)(1)(ii) and 79.3(a)(5) to permit approved markets that have the ability to maintain the identity of single source lots through the sale process to tag such animals after sale.

Movement, Premises ID, Group Lot Number

Several commenters requested clarification of the requirement to provide additional premises of a flock before unidentified animals were moved between those premises. In response we are adding the following clarification to § 79.3(a)(4): "A request to APHIS to enter additional flock premises in the National Scrapie Database is required before animals are first moved to the premises. Notification is not required for each subsequent movement of animals to that premises. Neither group lot ID nor an owner/hauler statement is required for movements of a flock or its members for flock management purposes within a contiguous premises spanning two or more States. This provision does not include the transiting or sale of animals through such a premises in circumvention of the other requirements of this part."

Several commenters requested additional clarification on how group/lot IDs may be used.

Group/lots IDs are used to (1) associate a unique number with movements of single source lots direct to slaughter or to a market to simplify identifying relevant records during a disease investigation, (2) to be able to easily differentiate groups of animals moved for management purposes such as grazing, and (3) to be able to quickly identify the sources of animals in multi-source lots such as slaughter lambs to assist in tracing exposed animals out of infected and source flocks to slaughter.

One commenter asked for clarification of the requirements in § 79.3(a). The commenter stated that the relationship between paragraph (a) and how that relates to animals over 18 months of age in slaughter channels was confusing. For example, the statement in (a) says that the animals in (1) through (5) may move with an owner/hauler statement and group lot ID, but then in (3) it refers to animals that have individual identification. The commenter asked if these requirements could be reworded.

We agree that this can be worded more clearly and have revised § 79.3(a)(3) to clarify that an owner/hauler statement may be used instead of an ICVI for such animals.

Indemnity

Four commenters noted that most American ewe lambs can be managed in a way that they can conceive at a young enough age to lamb as yearlings. The commenters believe that indemnifying for ewes that are verified as pregnant, regardless of their age, satisfies the general intention of age and reproduction status of the animals and that would apply to ewe lambs under 12 months of age. The commenters further stated that the proposed categorization of early maturing ewe lambs as yearlings could lead to disputes and mistakes with indemnity payments. The commenters therefore recommended removing the indemnity provision for early-maturing ewes and suggested indemnifying them based on their pregnancy status instead.

We agree with the commenters and have revised the program standards to reflect this by allowing animals under 12 months of age to be classified as yearlings only if they are visibly pregnant or have an offspring and not based on owner records indicating that the flock has a history of lambing or kidding at an early age. No changes to the regulations are necessary.

While preparing this final rule, we noted that there was substantial overlap between the provisions regarding indemnity in §§ 54.3(b) and 54.6(d). To improve clarity, we have

consolidated the provisions in § 54.3(b) and have removed § 54.6(d). We have also moved the provision allowing for the Administrator to waive the requirement for a flock plan or PEMMP from §§ 54.8(j)(3) to 54.8(l)

Paperwork

One commenter was concerned about the paperwork burden associated with the proposed rule. The commenter also expressed concern that the rule would require markets to provide seller information to all buyers.

The rule does increase the paperwork burden associated with maintaining tagging records, but we believe that maintaining these records for additional classes of goats and animals in slaughter channels is necessary to increase traceability of goats and sheep, which in turn is critical for eradicating scrapie. The rule does not require markets to provide seller information to buyers in most cases; the exception is that markets must provide the group lot numbers when the animals are moving unidentified as part of a single source lot in slaughter channels.

Program Standards

One commenter noted that there are references to the Scrapie SharePoint site throughout the program standards document. The commenter noted that State officials cannot currently access information on this site so another resource needs to be readily available and should replace all references to the Scrapie SharePoint site.

A SharePoint site accessible to State employees is now available.

One commenter noted that there are many references throughout the document to PEMMPs, particularly in Part VII and VIII and the flowcharts. The commenter stated that sometimes the term “full PEMMP” is used, sometimes the term “basic PEMMP” is used, and sometimes it is not specified. The commenter asked that APHIS clearly spell out what the

requirements are for each type of PEMMP, which type is required for each situation, and be consistent with terminology.

We have replaced the term “full PEMMP” with “retained susceptible animal PEMMP” throughout the program standards.

One commenter stated that some of the program standards definitions are slightly different from those in the rule.

Some of the definitions were not updated in the program standards and this has been corrected. Other definitions are slightly different because they need to reference the Code of Federal Regulations, and in some cases they include more specific information to assist the reader. Information that is subject to frequent change, such as the components currently included in the National Scrapie Database, was not put into the regulations.

One commenter asked what the purpose of entering low-risk exposed animals into the National Scrapie Database is.

The purpose of putting low-risk exposed animals in the database is to be able to search against the database if they should later be determined to be infected so that we can understand whether the criteria for redesignating animals as low-risk are effective and to be able to search against these animals when required for an export certificate or ICVI.

One commenter recommended not using Emergency Management and Response System (EMRS) for scrapie tracing.

We disagree. EMRS allows a higher degree of accountability for completing scrapie trace investigations and the number of trace outs is currently low enough that use of this system should not be overly burdensome.

One commenter asked what “when an insufficient number of QQ sheep and goats are available...” in the introduction to the *Part VII: Epidemiology A* section of the program standards meant.

We agree that this can be worded more clearly and are revising the Scrapie Program Standards to read “When the number of QQ sheep and goats in the flock is insufficient to conduct a reliable flock test, or...”

One commenter indicated that, in the *Part VII: Epidemiology B* section, the review provision in the note contradicted the table in that it indicates the Sheep and Goat Health Specialist for Epidemiology (SGHSE) must concur with decisions made by the designated scrapie epidemiologist.

The commenter is correct. We have corrected the table to list those situations when the SGHSE must approve the designation or re-designation and deleted the note.

One commenter stated that *Part VII: Epidemiology F. Procedures for Investigation and Monitoring a Flock that Received a High-Risk Animal* was hard to follow and should be revised for clarity.

We agree that there was room for improvement and have made edits for clarity.

One commenter stated that the term “status” had not been updated in places to conform with the change to SCS SCR.

We agree and have corrected the terminology to reflect the new nomenclature, which resulted from the migration of the Scrapie Program data from the Scrapie National Generic Database (SNGD) to SCS SCR, throughout the document. What was termed “status” in the SNGD is called a “program” or a “restriction” in SCS SCR.

One commenter recommended moving *Part VIII: Flock Cleanup Plans and PEMMPs B.3(a)(12), Steps for completing a standard genetic based flock plan for source and infected flocks that retain only AR, HR, KR, and RR ewes and male sheep and male goats*, to *Part VII: Epidemiology, E. B.3(b)(4)* because that section seems procedural and would fit better in Part VII.

We agree that this section could reasonably be moved to Part VII; however, we do not believe that it results in an improvement, so no change is being made in response to this comment.

One commenter requested that we provide VS Form 5-19c as an appendix to the program standards. The commenter also requested that we allow a State equivalent form.

We did not add the form as an appendix to the document to minimize the need to update the standards whenever a form is revised. The form has been approved under OMB control number 0579-0101 and will be available on the APHIS website. We agree that State equivalent forms may also be used and have updated the program standards accordingly.

One commenter asked APHIS to work with new and emerging registries to assure that their tattoo and radio frequency identification device implant systems are unique within the registry, retrievable, traceable, and that the registry rules allow for release of information to APHIS for regulatory disease purposes before these registry ID systems are accepted for the National Scrapie Eradication Plan.

APHIS intends to work with any new and emerging registries to ensure that their systems meet these requirements. We have also updated *Part III: Identification Requirements A(3)(b)(2)(a)* of the program standards to clarify the requirements for registry identification devices and methods.

Miscellaneous

While preparing this final rule, APHIS noted that we had used the phrase “premises that engages in interstate commerce” in several places in §§ 79.2 and 79.3. Since a premises cannot engage in an action, we have replaced that phrase with “premises where animals are received that have been in interstate commerce or from which animals are moved in interstate commerce.”

We have made nonsubstantive editorial changes to several sections to improve clarity. For the same reason we have divided § 54.8(j)(3) into two paragraphs. The provisions that appeared in that paragraph now appear in paragraphs (j)(3) and (l).

We have moved paragraph (3) of the definition of *Consistent State* in § 79.1 to a new paragraph (c) in § 79.6 because the provisions in that paragraph are more appropriately placed in that section.

One commenter recommended changing the name of the Scrapie Free Flock Certification Program to the Scrapie Certification Program to be consistent with the names of other disease certification programs.

We believe that changing the name of the program would be confusing and are making no changes in response to this comment.

Three commenters stated that they appreciate APHIS’ outreach efforts to producers, and that APHIS should increase access to educational resources for goat producers and veterinarians. The commenters stated that additional goat-specific resources would help to achieve best participation in the voluntary program and compliance with the regulations. The commenters further stated that APHIS should encourage on- farm submissions for scrapie surveillance and adequate records by producers for possible traceback.

APHIS agrees that goat-specific resources should be valuable and is working with the American Goat Federation to improve our education efforts directed to goat producers.

Comments Outside the Scope of the Rulemaking

One commenter expressed concern that scrapie poses a human health risk and stated that scrapie should be regulated in the same way as BSE. The commenter also stated that U.S. regulations governing BSE are too lax.

There is no epidemiologic evidence that scrapie of sheep and goats is transmitted to humans, such as through consumption, contact on the farm, at slaughter plants, or butcher shops. The regulations for control of scrapie and BSE are generally consistent with international guidelines. BSE is a separate disease from scrapie and can be distinguished using laboratory tests or mouse inoculation.

Some commenters made recommendations for changes to Scrapie Flock Certification Plan standards. We did not propose to make changes to those standards in this action; however they were taken into consideration when working on the revision of those standards.

Some commenters stated that APHIS should encourage future goat and sheep research and continue to collaborate with the Agricultural Research Service (ARS) to research scrapie diagnostic tests in live goats and scrapie control methods specific to goats. The commenters also stated that ARS should continue to research genetic resistance and susceptibility in goats and the pathogenesis and transmission of scrapie in goats and sheep.

We agree that these are important fields for research and have communicated these priorities to ARS.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Executive Orders 12866, 13563, 13771, and Regulatory Flexibility Act

This final rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget. This final rule is considered an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this final rule can be found in the rule's economic analysis.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also provides a final regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available on the Regulations.gov website (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

APHIS is amending the scrapie regulations to relieve certain restrictions associated with the interstate movement of sheep and goats, reduce the number of exposed sheep and goats that are destroyed, and improve overall program effectiveness. More specifically, genetic testing will be used to identify genetically resistant or less susceptible sheep for exemption from destruction and as qualifying for interstate movement; designated scrapie epidemiologists will be given greater flexibility in determining the testing needs of flocks; the indemnity regulations will be

changed to apply only to those animals that are found to be genetically susceptible to scrapie; official identification of goats produced for meat or fiber or that are slaughtered at over 18 months of age will be required; submission of tagging records by individuals who tag sheep or goats that do not originate on their premises will be required when requested; and certain recordkeeping requirements will be reduced, changed, or removed.

The primary benefits of this rule for producers and the public will be more rapid progress toward scrapie eradication and the related boost to the Nation's animal health status, decreased losses for producers, and increased export opportunities for sheep and goats and their products. Most segments and marketing channels of the sheep and goat industries will benefit from being able to operate under the new requirements and by the eradication of scrapie. By enhancing traceability, the rule will shorten the time and reduce the cost of eradication.

Producers of goats for meat or fiber and slaughter goats over 18 months of age will incur costs of official identification as a result of the rule. However, we note that close to one-half of goat farms (that is, all dairy and breeding goat farms except low-risk commercial operations) are already required to be in compliance with the identification requirements under current regulations.

The rule will affect sheep and goat producers, marketers and dealers, most of which are small entities. As noted in the regulatory impact analysis, individuals may spend about 2 hours a year on recordkeeping, at a time cost of about \$34.50, but in fact many of these records of sales and purchases are typically already kept as a normal business practice. Based on 2012 Census of Agriculture data, this cost if incurred would equal about 1.5 percent of average revenue for meat goat producers. We expect these entities to find the rule's official identification requirements

and other conditions well worth the cost. This rule will not pose a large cost burden for entities, large or small.

Eradication of scrapie will enable APHIS to negotiate removal of the varying current restrictions and allow an expansion of exports. Based on cited simulation modeling of the economic benefits of eradication of scrapie and certain other animal diseases, gains from trade are expected to exceed the recordkeeping, tagging, and other costs that producers and other entities will incur.

The trade gains realized can be interpreted as cost savings from no longer being subject to certain import restrictions imposed by other countries. Based on measures of increased welfare due to expanded exports, and in accordance with guidance on complying with Executive Order 13771, the primary estimate of the rule's annual cost savings is \$115,000, the mid-point estimate annualized in perpetuity using a 7 percent discount rate.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR Chapter IV.)

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175 "Consultation and Coordination with Indian Tribal Governments." Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

APHIS has assessed the impact of this rule on Indian Tribes and determined that this rule does not, to our knowledge, have tribal implications that require Tribal consultation under Executive Order 13175. If a tribe requests consultation, APHIS will work with the USDA Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), some of the information collection requirements included in this final rule are approved under Office of Management and Budget (OMB) control number 0579-0101. The new information collection requirements included in this final rule, which were filed with comment under OMB control number 0579-0469, have been submitted for approval to OMB. When OMB notifies us of its decision, if approval is denied, we will publish a document in the *Federal Register* providing notice of what action(s) we plan to take.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483.

List of Subjects

9 CFR Part 54

Animal diseases, Goats, Indemnity payments, Scrapie, Sheep.

9 CFR Part 79

Animal diseases, Quarantine, Sheep, Transportation.

Accordingly, we are amending 9 CFR parts 54 and 79 as follows:

PART 54--CONTROL OF SCRAPIE

1. The authority citation for part 54 continues to read as follows:

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

2. Section 54.1 is amended as follows:

a. By removing the definition for *Approved test*;

b. In the definition for *Breed association and registries*, by removing the words “listed in § 151.9 of this chapter”;

c. By removing the definition for *Certificate*;

d. By adding in alphabetical order a definition for *Classification or reclassification investigation*;

- e. In the heading of the definition for *Designated scrapie epidemiologist*, by adding the acronym “DSE” immediately after “epidemiologist”;
- f. By revising the definitions for *Destroyed*, *Exposed animal*, and *Exposed flock*;
- g. In the definition for *Flock*, paragraph (2)(v), by adding the word “Free” between the words “Scrapie” and “Flock”;
- h. In the definition for *Flock plan*, by removing the paragraph designation “(f)” and by adding the paragraph designation “(j)” in its place;
- i. By revising the definition for *Flock sire*;
- j. By adding in alphabetical order definitions for *Flock under investigation*, *Genetically less susceptible exposed sheep*, *Genetically resistant exposed sheep*, *Genetically resistant sheep*, *Genetically susceptible animal*, and *Genetically susceptible exposed animal*;
- k. By revising the definition for *High-risk animal*;
- l. By adding in alphabetical order a definition for *Interstate certificate of veterinary inspection (ICVI)*;
- m. In the definition for *Limited contacts*, by adding the word “Free” between the words “Scrapie” and “Flock” in the last sentence;
- n. By adding in alphabetical order a definition for *Low-risk exposed animal*;
- o. In the definition for *National Scrapie Database*, by adding the word “Free” between the words “Scrapie” and “Flock”; and
- p. By amending the definition for *Noncompliant flock* as follows:
 - i. In paragraph (1), by removing the words “source or infected flock” and adding the words “source, infected, or exposed flock or flock under investigation” in their place;

ii. In paragraph (2), by adding the words “or flock under investigation” immediately after the words “exposed flock”; and

iii. In paragraph (3), by removing the words “owner statement” and adding the words “owner/hauler statement” in their place.

q. By revising the definition for *Official genotype test*;

r. By adding in alphabetical order definitions for *Program approved test* and *Restricted animal sale or restricted livestock facility*;

s. In the heading of the definition for *Scrapie Flock Certification Program (SFCP)*, by adding the word “Free” immediately after the word “Scrapie”;

t. In the heading of the definition for *Scrapie Flock Certification Program standards*, by adding the word “Free” immediately after the word “Scrapie” and, in footnote 2, by removing the internet address “<http://www.aphis.usda.gov/vs/scrapie>” and adding the internet address “<http://www.aphis.usda.gov/animal-health/scrapie>” in its place;

u. In the definition for *Scrapie-positive animal*, in paragraph (2), by adding the words “, and/or ELISA,” immediately after the word “immunohistochemistry” and, in paragraph (5), by removing the words “test method” and adding the words “method or combination of methods” in their place;

v. By removing the definition for *Separate contemporary lambing group*;

w. By revising the definition for *Slaughter channels*;

x. By revising paragraph (1) in the definition of *Suspect animal*; and

y. By adding in alphabetical order definitions for *Tamper-resistant sampling kit* and *Terminal feedlot*.

The additions and revisions read as follows:

§ 54.1 Definitions.

* * * *

Classification or reclassification investigation. An epidemiological investigation conducted or directed by a DSE for the purpose of designating or redesignating the status (e.g., scrapie-positive, exposed, high-risk, suspect, infected, noncompliant, source, etc.) of a flock or animal. In conducting such an investigation, the DSE will evaluate the available records for flocks and individual animals and conduct or direct any testing needed to assess the status of a flock or animal. The status of an animal or flock will be determined based on the applicable definitions in this section and, when needed to make a designation under § 79.4 of this chapter, official genotype test results, exposure risk, scrapie type involved, results of official scrapie testing on live or dead animals, or any combination of these.

* * * *

Destroyed. Euthanized and the carcass disposed of by means authorized by the Administrator that will prevent its use as feed or food.

* * * *

Exposed animal. Any animal or embryo that:

- (1) Has been in a flock with a scrapie-positive female animal;
- (2) Has been in an enclosure with a scrapie-positive female animal at any location;
- (3) Resides in a noncompliant flock; or

(4) Has resided on the premises of a flock before or while it was designated by a DSE an infected or source flock and before a flock plan was completed. An animal shall not be designated an exposed animal if it only resided on the premises before the date that infection was most likely introduced to the premises as determined by a Federal or State representative. If the

probable date of infection cannot be determined based on the epidemiologic investigation, a date 2 years before the birth of the oldest scrapie-positive animal born in that flock will be used. If the actual birth date is unknown, the date of birth will be estimated based on examination of the teeth and any available records. If an age estimate cannot be made, the animal will be assumed to have been 48 months of age on the date samples were collected for scrapie diagnosis.

Exposed animals will be further designated as genetically resistant exposed sheep, genetically less susceptible exposed sheep, genetically susceptible exposed animals, or low-risk exposed animals. An animal will no longer be an exposed animal if it is redesignated in accordance with § 79.4 of this chapter.

Exposed flock. (1) Any flock that was designated by a DSE as an infected or source flock that has completed a flock plan, and that retained a female genetically susceptible exposed animal;

(2) Any flock under investigation that retains a female genetically susceptible exposed animal or a suspect animal, or whose owner declines to complete genotyping and live-animal and/or post-mortem scrapie testing required by the APHIS or State representative investigating the flock; or

(3) Any noncompliant flock or any flock for which a PEMMP is required that is not in compliance with the conditions of the PEMMP.

* * * * *

Flock sire. A sexually intact male animal that has produced offspring in the preceding 12 months or that was used for breeding during the current breeding cycle.

Flock under investigation. Any flock in which an APHIS or State representative has determined that a scrapie-suspect animal, high-risk animal, or scrapie-positive animal resides or may have resided.

Genetically less susceptible exposed sheep. Any sheep or sheep embryo that is:

(1) An exposed sheep or sheep embryo of genotype AA QR, unless the Administrator determines that it is epidemiologically linked to a scrapie-positive RR or AA QR sheep or to a scrapie type to which AA QR sheep are not less susceptible; or

(2) An exposed sheep or sheep embryo of genotype AV QR, unless the Administrator determines that it is epidemiologically linked to a scrapie-positive RR or QR sheep, to a flock that the Administrator has determined may be affected by valine-associated scrapie (based on an evaluation of the genotypes of the scrapie-positive animals linked to the flock), or to another scrapie type to which AV QR sheep are not less susceptible; or

(3) An exposed sheep or sheep embryo of a genotype that has been exposed to a scrapie type to which the Administrator has determined that genotype is less susceptible.

In this definition R refers to codon 171 and A refers to codon 136, and Q represents any genotype other than R at codon 171 and V represents any genotype other than A at codon 136.

Genetically resistant exposed sheep. Any exposed sheep or sheep embryo of genotype RR at codon 171 unless the Administrator determines that it is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type to which RR sheep are not resistant.

Genetically resistant sheep. Any sheep or sheep embryo of genotype RR at codon 171 unless the Administrator determines that it is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type that affects RR at codon 171 sheep.

Genetically susceptible animal. Any goat or goat embryo, sheep or sheep embryo of a genotype other than RR or QR, where Q represents any genotype other than R at codon 171 or sheep or sheep embryo of undetermined genotype.

Genetically susceptible exposed animal. Excluding low-risk exposed animals, any exposed animal or embryo that is also:

- (1) A genetically susceptible animal; or
- (2) A sheep or sheep embryo of genotype AV QR that the Administrator determines is epidemiologically linked to a scrapie-positive RR or QR sheep, to a flock that the Administrator has determined may be affected by valine-associated scrapie (based on an evaluation of the genotypes of the scrapie-positive animals linked to the flock), or to a scrapie type to which AV QR sheep are susceptible; or
- (3) A sheep or sheep embryo of genotype AA QR that the Administrator determines is epidemiologically linked to a scrapie-positive RR or AA QR sheep or to a scrapie type to which AA QR sheep are susceptible; or
- (4) A sheep or sheep embryo of genotype RR that the Administrator determines is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type to which RR sheep are susceptible.

(5) NOTE: In this definition R refers to codon 171 and A refers to codon 136, and Q represents any genotype other than R at codon 171 and V represents any genotype other than A at codon 136.

High-risk animal. The female offspring or embryo of a scrapie-positive female animal, or any suspect animal, or a female genetically susceptible exposed animal, or any exposed animal that the Administrator determines to be a potential risk. The Administrator may base the

determination that an exposed animal poses a potential risk on the scrapie type, the epidemiology of the flock or flocks with which it is epidemiologically linked, including genetics of the positive sheep, the prevalence of scrapie in the flock, any history of recurrent infection, and other flock or animal characteristics. An animal will no longer be a high-risk animal if it is redesignated in accordance with § 79.4 of this chapter.

* * * * *

Interstate certificate of veterinary inspection (ICVI). An official document issued by a Federal, State, Tribal, or accredited veterinarian certifying the inspection of animals in preparation for interstate movement or other uses as described in this part and in accordance with § 79.5 of this chapter.

* * * * *

Low-risk exposed animal. Any exposed animal to which the Administrator has determined one or more of the following applies:

- (1) The positive animal that was the source of exposure was not born in the flock and did not lamb in the flock or in an enclosure where the exposed animal resided;
- (2) The Administrator and State representative concur that the animal is unlikely to be infected due to factors such as, but not limited to, where the animal resided or the time period the animal resided in the flock;
- (3) The exposed animal is male and was not born in an infected or source flock;
- (4) The exposed animal is a castrated male;
- (5) The exposed animal is an embryo of a genetically resistant exposed sheep or a genetically less susceptible exposed sheep unless placed in a recipient that was a genetically susceptible exposed animal; or

(6) The animal was exposed to a scrapie type and/or is of a genotype that the Administrator has determined poses low risk of scrapie transmission.

* * * * *

Official genotype test. A test to determine the genotype of a live or dead animal conducted at either the National Veterinary Services Laboratories or at an approved laboratory. The test subject must be an animal that is officially identified and the test accurately recorded on an official form supplied or approved by APHIS, with the samples collected and shipped to the laboratory using a shipping method specified by the laboratory by:

- (1) An accredited veterinarian;
- (2) A State or APHIS representative; or
- (3) The animal's owner or owner's agent, using a tamper-resistant sampling kit approved by APHIS for this purpose.

* * * * *

Program approved test. A test for the diagnosis of scrapie approved by the Administrator for use in the scrapie eradication or certification program in accordance with § 54.10.

Restricted animal sale or restricted livestock facility. A sale where any animals in slaughter channels are maintained separate from other animals not in slaughter channels unless they are from the same flock of origin and are sold in lots that consist entirely of animals sold for slaughter only, or a livestock facility at which all animals are in slaughter channels, and where the sale or facility manager maintains a copy of, or maintains a record of, the information from the owner/hauler statement for all animals entering and leaving the sale or facility. A restricted animal sale may be held at a livestock facility that is not restricted.

* * * *

Slaughter channels. Animals in slaughter channels include any animal that is sold, transferred, or moved either directly to or through a restricted animal sale or restricted livestock facility to an official slaughter establishment that is under Food Safety and Inspection Service (FSIS) jurisdiction per the Federal Meat Inspection Act (FMIA) or under State inspection that FSIS has recognized as at least equal to Federal inspection or to a custom exempt slaughter establishment as defined by FSIS (9 CFR 303.1) for immediate slaughter or to an individual for immediate slaughter for personal use or to a terminal feedlot.

* * * *

Suspect animal. * * *

(1) A mature sheep or goat as evidenced by eruption of the first incisor that has been condemned by FSIS or a State inspection authority for central nervous system (CNS) signs, or that exhibits any of the following clinical signs of scrapie and has been determined to be suspicious for scrapie by an accredited veterinarian or a State or USDA representative, based on one or more of the following signs and the severity of the signs: Weakness of any kind including, but not limited to, stumbling, falling down, or having difficulty rising, not including those with visible traumatic injuries and no other signs of scrapie; behavioral abnormalities; significant weight loss despite retention of appetite or in an animal with adequate dentition; increased sensitivity to noise and sudden movement; tremors; star gazing; head pressing; bilateral gait abnormalities such as but not limited to incoordination, ataxia, high stepping gait of forelimbs, bunny-hop movement of rear legs, or swaying of back end, but not including abnormalities involving only one leg or one front and one back leg; repeated intense rubbing with bare areas or damaged wool in similar locations on both sides of the animal's body or, if on

the head, both sides of the poll; abraded, rough, thickened, or hyperpigmented areas of skin in areas of wool/hair loss in similar locations on both sides of the animal's body or, if on the head, both sides of the poll; or other signs of CNS disease. An animal will no longer be a suspect animal if it is redesignated in accordance with § 79.4 of this chapter.

* * * * *

Tamper-resistant sampling kit. A device or method for collecting DNA samples from sheep or goats that is approved by the Administrator and that identifies both the sample and the animal at the time the sample is collected. These devices or methods must ensure that the sample, its corresponding label, and the official ID device or method applied to the animal meets the requirements of § 79.2(k) of this chapter and that the sample is from the same animal to which the official ID device or method was applied. The kit must include an APHIS-approved official form or another form, device, or method acceptable to APHIS for transmitting the information required to APHIS and the approved laboratory.

Terminal feedlot. (1) A dry lot approved by a State or APHIS representative or an accredited veterinarian who is authorized by the Administrator to perform this function where animals in the terminal feedlot are separated from all other animals by at least 30 feet at all times or are separated by a solid wall through, over, or under which fluids cannot pass and contact cannot occur and must be cleaned of all organic material prior to being used to contain sheep or goats that are not in slaughter channels, where only castrated males are maintained with female animals and from which animals are moved only to another terminal feedlot or directly to slaughter; or

(2) A dry lot approved by a State or APHIS representative or an accredited veterinarian who is authorized by the Administrator to perform this function where only animals that either

are not pregnant based on the animal being male, an owner certification that any female animals have not been exposed to a male in the preceding 6 months, an ICVI issued by an accredited veterinarian stating the animals are not pregnant, or the animals are under 6 months of age at time of receipt, where only castrated males are maintained with female animals, and all animals in the terminal feedlot are separated from all other animals such that physical contact cannot occur including through a fence and from which animals are moved only to another terminal feedlot or directly to slaughter; or

(3) A pasture when approved by and maintained under the supervision of the State and in which only nonpregnant animals are permitted based on the animal being male, an owner certification that any female animals have not been exposed to a male in the preceding 6 months, or an ICVI issued by an accredited veterinarian stating the animals are not pregnant, or the animals are under 6 months of age at time of receipt, where only castrated males are maintained with female animals, where there is no direct fence-to-fence contact with another flock, and from which animals are moved only to another terminal feedlot or directly to slaughter.

(4) Records of all animals entering and leaving a terminal feedlot must be maintained for 5 years after the animal leaves the feedlot and must meet the requirements of § 79.2 of this chapter, including either a copy of the required owner/hauler statements for animals entering and leaving the facility or the information required to be on the statements. Records must be made available for inspection and copying by an APHIS or State representative upon request.

* * * * *

§ 54.2 [Amended]

3. Section 54.2 is amended by adding the word “Free” between the words “Scrapie” and “Flock” each time they appear.

4. Section § 54.3 is amended by revising paragraph (b) and adding an OMB citation at the end of the section to read as follows:

§ 54.3 Animals eligible for indemnity payments.

* * * * *

(b) Indemnity will be paid to an owner only for animals actually in a flock at the time indemnity is first offered in writing, and for offspring born to animals in that flock within 60 days after the time indemnity is first offered in writing. Animals removed from the flock as part of an investigation or a post-exposure management and monitoring plan (PEMMP) will be paid indemnity based on the calculated prices at the time an APHIS representative designates, in writing, the animals for removal. If an owner declines to remove an animal within 60 days of when indemnity is first offered the owner will receive the lower value of when indemnity was first offered in writing or when the animal was actually removed. APHIS may withdraw an indemnity offer if an owner does not make animals available for inventory, gestational assessment, and testing within 30 days, does not remove an animal within 60 days of the written indemnity offer or by the date specified in a flock plan or PEMMP, or fails to provide APHIS animal registration certificates, sale and movement records, or other records requested in accordance with § 54.5. No indemnity will be paid for any animal, or the progeny of any animal, that has been moved or handled by the owner in violation of the requirements of the Animal Health Protection Act or the regulations promulgated thereunder. No indemnity will be paid for an animal added to the premises while a flock is under investigation or while it is an infected or source flock other than natural additions. No indemnity will be paid for natural additions born more than 60 days after the owner is notified they are eligible for indemnity unless the Administrator makes a determination that the dam could not be removed within the allowed time

as a result of conditions outside the control of the owner. No indemnity will be paid unless the owner has signed and is in compliance with the requirements of a flock plan or post-exposure management and monitoring plan (PEMMP) as described in § 54.8 unless the requirement for a flock plan or PEMMP has been waived by the Administrator. No indemnity will be paid until the premises, including all structures, holding facilities, conveyances, and materials contaminated because of occupation or use by the depopulated animals, have been properly cleaned and disinfected in accordance with § 54.7(e), unless premises or portions of premises have been exempted from the cleaning and disinfecting requirements per § 54.8(j)(1); Except that, partial indemnity may be paid when the Administrator determines that weather or other factors outside the control of the owner make immediate disinfection impractical. No indemnity will be paid to an owner for any animals if the owner established or increased his flock for the purpose of collecting or increasing indemnity.

(Approved by the Office of Management and Budget under control number 0579-0101)

5. Section 54.4 is amended by revising paragraph (a)(5) and adding an OMB citation at the end of the section to read as follows:

§ 54.4 Application by owners for indemnity payments.

(a) * * *

(5) A copy of the registration papers issued in the name of the owner for any registered animals in the flock (registration papers are not required for the payment of indemnity for animals that are not registered); and

* * * * *

(Approved by the Office of Management and Budget under control number 0579-0101)

6. Section 54.5 is amended as follows:

- a. In paragraph (d), by removing the word “slaughtered,”; and
- b. By adding an OMB citation at the end of the section.

The addition reads as follows:

§ 54.5 Certification by owners.

* * * * *

(Approved by the Office of Management and Budget under control number 0579-0101)

7. Section 54.6 is revised to read as follows:

§ 54.6 Amount of indemnity payments.

(a) *Indemnity.* Indemnity paid for sheep and goats in accordance with § 54.3 will be the fair market value of the animals. APHIS' determination of fair market value will be based on available price report data that most accurately reflect the type of animal being indemnified and the time at which the animal was indemnified. Premiums will be paid for certain types of sheep and goats, including, but not limited to: Registered animals, flock sires, pregnant animals and early-maturing ewes; Except that, no premium will be added for animals of any age that were in slaughter channels when indemnity was offered. To calculate indemnity, APHIS will use price information provided by the Agricultural Marketing Service (AMS) or other available price information and any other data necessary to establish the value of different types of sheep and goats. A detailed description of the methods APHIS uses to calculate indemnity for sheep and goats is available at <http://www.aphis.usda.gov/animal-health/scrapie>.

(b) *Age and number of animals.* If records and identification are inadequate to determine the actual age of animals, an APHIS or State representative will count all sexually intact animals that are apparently under 1 year of age, and those that are apparently at least 1 and under 2 years of age, based on examination of their teeth, and the indemnity for these animals will be

calculated. The total number of these animals will be subtracted from the total number of sexually intact animals in the group to be indemnified, and indemnity for the remainder will be calculated based on the assumption that the remainder of the flock is 80 percent aged 2 to 6 years and 20 percent aged 6 to 8 years.

(c) *Animal weights.* If the owner disagrees with the average weight estimate, he may have the animals weighed at a public scale at his own expense, provided that the animals may not come in contact with other sheep or goats during movement to the public scales, and will be paid based on the actual weight multiplied by the price per pound for the class of animal as calculated in paragraph (a) of this section.

(Approved by the Office of Management and Budget under control number 0579-0101)

8. Section 54.7 is amended as follows:

a. By revising paragraphs (a) and (d);

b. In paragraph (e), introductory text, by removing the words “Scrapie Flock Certification Program standards and the Scrapie Eradication Uniform Methods and Rules” adding in their place “Scrapie Program Standards Volume 1: National Scrapie Eradication Program and Scrapie Program Standards Volume 2: Scrapie Free Flock Certification Program (SFCP)”;

c. In paragraph (e)(1), by removing the words “animals or wildlife” and adding in their place the words “or wild ruminants”;

d. By revising paragraph (e)(2) introductory text;

e. By removing paragraph (e)(2)(i), redesignating paragraphs (e)(2)(ii) and (iii) as paragraphs (e)(2)(i) and (ii), respectively, and by adding new paragraphs (e)(2)(iii) and (iv); and

f. By adding an OMB citation at the end of the section.

The revisions and additions read as follows:

§ 54.7 Procedures for destruction of animals.

(a) Animals for which indemnification is sought must be destroyed on the premises where they are held, pastured, or penned at the time indemnity is approved or moved to an approved research facility, unless the APHIS representative involved approves in advance of destruction moving the animals to another location for destruction.

* * * * *

(d) APHIS may pay the reasonable costs of disposal for animals that are indemnified. To obtain reimbursement for disposal costs, animal owners must obtain written approval of the disposal costs from APHIS, prior to disposal. For reimbursement to be made, the owner of the animals must present the Veterinary Services, Field Operations, Area Veterinarian in Charge (AVIC) responsible for the State involved with a copy of either a receipt for expenses paid or a bill for services rendered. Any bill for services rendered by the owner must not be greater than the normal fee for similar services provided by a commercial hauler or disposal facility.

(e) * * *

(2) *Cement, wood, metal and other non-earth surfaces, tools, equipment, instruments, feed, hay, bedding, and other materials.* Organic and/or inorganic materials may be disposed of by incineration or burial. Inorganic material and wood structures may be cleaned and disinfected. To disinfect, remove all organic material and incinerate, bury, till under, or compost the removed organic material in areas not accessed by domestic or wild ruminants until it can be incinerated, buried, or tilled under. Clean and wash all surfaces, tools, equipment, and instruments using hot water and detergent. Allow all surfaces, tools, equipment, and instruments to dry completely before disinfecting and sanitizing using one of the following methods:

* * * * *

(iii) Use a product registered by the U.S. Environmental Protection Agency (EPA) specifically for reduction of prion infectivity at these sites in accordance with the label.

(iv) Use a product in accordance with an emergency exemption issued by the EPA for reduction of prion infectivity at these sites.

(Approved by the Office of Management and Budget under control number 0579-0469)

9. Section 54.8 is revised to read as follows:

§ 54.8 Requirements for flocks under investigation and flocks subject to flock plans and post-exposure management and monitoring plans.

(a) For animals in a flock under investigation, flock plan, or post-exposure management and monitoring plan (PEMMP), the official identification must provide a unique identification number that is applied by the owner of the flock or his or her agent and must be linked to that flock in the National Scrapie Database. APHIS may specify the type of official identification that may be used in order to maximize retention of the means of identification, identify restricted or test positive animals or to facilitate the testing or inventory of the animals. The owner of the flock or his or her agent must officially identify and maintain the identity of:

(1) All animals in the flock while it is subject to a flock plan or PEMMP;

(2) Any high-risk or genetically susceptible exposed animals in the flock and any other restricted animals;

(3) Any animals designated for testing by an APHIS representative or State representative until testing is completed, results reported, and animals classified; and

(4) All sexually intact animals, all exposed animals, and animals 18 months of age and older (as evidenced by the eruption of the second incisor) prior to a change in ownership and before they are moved off the premises of the flock.

(b) For flocks under a flock plan or PEMMP, the flock owner must maintain the following records for 5 years or until the flock plan and/or PEMMP is completed, whichever is longer.

(1) For acquired animals, the date of acquisition, name and address of the person from whom the animal was acquired, any identifying marks, or identification devices present on the animal including but not limited to the animal's individual official identification number(s) from its electronic implant, flank tattoo, ear tattoo, tamper-resistant eartag, or, in the case of goats, tail fold tattoo, and any secondary form of identification the owner of the flock may choose to maintain and the records required by § 79.2 of this chapter.

(2) For animals leaving the premises of the flock, the disposition of the animal, including, any identifying marks or identification devices present on the animal, including but not limited to the animal's individual official identification number from its electronic implant, flank tattoo, ear tattoo, tamper-resistant eartag, or, in the case of goats, a tail fold tattoo, and any secondary form of identification the owner of the flock may choose to maintain, the date and cause of death, if known, or date of removal from the flock and name and address of the person to whom the animal was transferred and the records required by § 79.2 of this chapter.

(c) Upon request by a State or APHIS representative or as required in a PEMMP, the owner of the flock or his or her agent must have an accredited veterinarian collect tissues from animals for scrapie diagnostic purposes and submit them to a laboratory designated by a State or APHIS representative or collect and submit samples by another method acceptable to APHIS.

(d) Upon request by a State or APHIS representative, the owner of the flock or his or her agent must make animals in the flock available for inspection and or testing and the records required to be kept as a part of these plans available for inspection and copying.

(e) The owner of the flock or his or her agent must meet requirements found necessary by a DSE to monitor for scrapie and to prevent the recurrence of scrapie in the flock and to prevent the spread of scrapie from the flock. These other requirements may include, but are not limited to: Utilization of a live-animal screening test; reporting animals found dead and collecting and submitting test samples from them; restrictions on the animals that may be moved from the flock; use of genetically resistant rams; segregated lambing; cleaning and disinfection of lambing facilities; and/or education of the owner of the flock and personnel working with the flock in techniques to recognize clinical signs of scrapie and to control the spread of scrapie.

(f) The owner of the flock or his or her agent must immediately report the following animals to a State representative, APHIS representative, or an accredited veterinarian; ensure that samples are properly collected for testing if the animal dies; allow the animals to be tested, and not remove them from a flock without written permission of a State or APHIS representative:

(1) Any sheep or goat exhibiting weight loss despite retention of appetite; behavioral abnormalities; pruritus (itching); wool pulling; wool loss; biting at legs or side; lip smacking; motor abnormalities such as incoordination, high stepping gait of forelimbs, bunny hop movement of rear legs, or swaying of back end; increased sensitivity to noise and sudden movement; tremor; star gazing; head pressing; recumbency; rubbing, or other signs of neurological disease or chronic wasting illness; and

(2) Any sheep or goat in the flock that has tested positive for scrapie or for the proteinase resistant protein associated with scrapie on a live-animal screening test or any other test.

(g) An epidemiologic investigation must be conducted to identify high-risk and exposed animals that currently reside in the flock or that previously resided in the flock, and all high-risk animals, scrapie-positive animals, and suspect animals must be removed from the flock except as

provided in paragraph (h) of this section. The animals must be removed either by movement to an approved research facility or by euthanasia and disposal of the carcasses by burial, incineration, or other methods approved by the Administrator and in accordance with local, State, and Federal laws, or upon request in individual cases by another means determined by the Administrator to be sufficient to prevent the spread of scrapie.

(h) The Administrator may allow high-risk animals that are not suspect animals to be retained under restriction if they are not genetically susceptible animals or if they have tested “PrPsc not detected” on a live animal scrapie test approved for this purpose by the Administrator and are maintained in a manner that the Administrator determines minimizes the risk of scrapie transmission, e.g., bred only to genetically resistant sheep, segregated for lambing, and cleaning and disinfection of the lambing area. Such animals may be retained only if the exempted animal’s official identification and the requirements for minimizing the risk of scrapie transmission are documented in the PEMMP and the owner is in compliance with the PEMMP. All such animals must be tested for scrapie when they are euthanized or die or if they are later determined to be suspect animals.

(i) The owner of the flock, or his or her agent, must request breed associations and registries, livestock facilities, and packers to disclose records to APHIS representatives or State representatives, to be used to identify source flocks and trace exposed animals, including high-risk animals.

(j) The flock plan will include a description of the types of animals that must be removed from a flock, the timeframes in which they must be removed and any other actions that must be accomplished in order for the flock plan to be completed. Flock plans shall require an owner to agree to:

(1) Clean and disinfect the premises in accordance with § 54.7(e). Premises or portions of premises may be exempted from the cleaning and disinfecting requirements if a designated scrapie epidemiologist determines, based on an epidemiologic investigation, that cleaning and disinfection of such buildings, holding facilities, conveyances, or other materials on the premises will not significantly reduce the risk of the spread of scrapie, either because effective disinfection is not possible or because the normal operations on the premises prevent transmission of scrapie. No confined area where a scrapie-positive animal was born, lambled or aborted may be exempted;

(2) Agree to conduct a post-exposure management and monitoring plan (PEMMP); and

(3) Comply with any other conditions in the flock plan;

(k) A PEMMP will be required for exposed flocks and may be required for flocks under investigation that were not source or infected flocks. A PEMMP may also be required for flocks that formerly were exposed flocks or flocks under investigation as a condition for being redesignated. A designated scrapie epidemiologist shall determine when to require a PEMMP and the monitoring requirements for these flocks based on the findings of the classification or reclassification investigation.

(l) Provided that, the Administrator may waive the requirement for a flock plan or PEMMP or waive any of the requirements in a flock plan or PEMMP after determining that the flock poses a low risk of scrapie transmission.

(Approved by the Office of Management and Budget under control numbers 0579-0101 and 0579-0469)

10. Section 54.10 is revised to read as follows:

§ 54.10 Program approval of tests for scrapie.

(a) The Administrator may approve new tests or test methods for the diagnosis of scrapie conducted on live or dead animals for use in the Scrapie Eradication Program and/or the Scrapie Free Flock Certification Program. The Administrator will base the approval or disapproval of a test on the evaluation by APHIS and, when appropriate, outside scientists, of:

(1) A standardized test protocol that must include a description of the test, a description of the reagents, materials, and equipment used for the test, the test methodology, and any control or quality assurance procedures;

(2) Data to support repeatability, that is, the ability to reproduce the same result repeatedly on a given sample;

(3) Data to support reproducibility, that is, data to show that similar results can be produced when the test is run at other laboratories;

(4) Data to support the diagnostic and in the case of assays the analytical sensitivity and specificity of the test; and

(5) Any other data or information requested by the Administrator to determine the suitability of the test for program use. This may include but is not limited to past performance, cost of test materials and equipment, ease of test performance, generation of waste, and potential use of existing equipment.

(b) To be approved for program use, a scrapie test must be able to be readily and successfully performed at the National Veterinary Services Laboratories.

(c) The test must have a reliable, timely, and cost effective method of proficiency testing.

(d) The Administrator may decline to evaluate any test kit for program approval that has not been licensed for the intended use and may decline to evaluate any test or test method for

program use unless the requester can demonstrate that the new method offers a significant advantage over currently approved methods.

(e) A test or combination of tests may be approved for the identification of suspect animals, or scrapie-positive animals, or for other purposes such as flock certification. For a test to be approved for the identification of scrapie-positive animals, the test must demonstrate a diagnostic specificity comparable to that of current program-approved tests, and the sensitivity of the test will also be considered in determining the approved uses of the test within the program. For a test to be approved for the removal of high-risk, exposed, or suspect animal designations the test must have a diagnostic sensitivity at least comparable to that of current program-approved tests used for this purpose. Since the purpose of a screening test is usually to identify a subset of animals for further testing, for a test to be approved as a screening test for the identification of suspect animals, the test must be usually reliable but need not be definitive for diagnosing scrapie.

(f) Specific guidelines for use of program-approved tests within the Scrapie Eradication Program or Scrapie Free Flock Certification Program will be made available on the scrapie website at <http://www.aphis.usda.gov/animal-health/scrapie>. Guidelines will be based on the characteristics of the test, including specificity, sensitivity, and predictive value in defined groups of animals.

(g) If an owner elects to have an unofficial test conducted on an animal for scrapie, or for the proteinase resistant protein associated with scrapie, and that animal tests positive to such a test, the animal will be designated a suspect animal, unless the test is conducted as part of a research protocol and the protocol includes appropriate measures to prevent the spread of scrapie.

(h) The Administrator may withdraw or suspend approval of any test or test method if the test or method does not perform at an acceptable level following approval or if a more effective test or test method is subsequently approved. The Administrator shall give written notice of the suspension or proposed withdrawal to the director of the laboratories using the test or method or in the case of test kits to the manufacturer and shall give the director or manufacturer an opportunity to respond. Such action shall become effective upon oral or written notification, whichever is earlier, to the laboratory or manufacturer. If there are conflicts as to any material fact concerning the reason for withdrawal, a hearing may be requested in accordance with the procedure in § 79.4(c)(3) of this chapter. The action under appeal shall continue in effect pending the final determination of the Administrator, unless otherwise ordered by the Administrator. The Administrator's final determination constitutes final agency action.

(Approved by the Office of Management and Budget under control number 0579-0469)

11. Section 54.11 is revised to read as follows:

§ 54.11 Approval of laboratories to run official scrapie tests and official genotype tests.

(a) State, Federal, and university laboratories, or in the case of genotype tests, private laboratories will be approved by the Administrator when he or she determines that the laboratory:

(1) Employs personnel assigned to supervise and conduct the testing who are qualified to conduct the test based on education, training, and experience and who have been trained by the National Veterinary Services Laboratories (NVSL) or who have completed equivalent training approved by NVSL;

(2) Has adequate facilities and equipment to conduct the test;

(3) Follows standard test protocols that are approved or provided by NVSL;

(4) Meets check test proficiency requirements and consistently produces accurate test results as determined by NVSL review;

(5) Meets recordkeeping requirements;

(6) Will retain records, slides, blocks, and other specimens from all cases for at least 1 year and from positive cases and DNA from all genotype tests for at least 5 years and will forward copies of records and any of these materials to NVSL within 5 business days of request; Except that, NVSL may authorize a shorter retention time in a standard operating procedure or contract;

(7) Will allow APHIS to inspect the laboratory without notice during normal business hours. An inspection may include, but is not limited to, review and copying of records, examination of slides, review of quality control procedures, observation of sample handling/tracking procedures, observation of the test being conducted, and interviewing of personnel;

(8) Will report all test results to State and Federal animal health officials and record them in the National Scrapie Database within timeframes and in the manner and format specified by the Administrator; and

(9) Complies with any other written guidance provided to the laboratory by the Administrator.

(b) A laboratory may request approval to conduct one or more types of program-approved scrapie test or genotype test on one or more types of tissue. To be approved, a laboratory must meet the requirements in paragraph (a) of this section for each type of test and for each type of tissue for which they request approval.

(c) The Administrator may suspend or withdraw approval of any laboratory for failure to meet any of the conditions required by paragraph (a) of this section. The Administrator shall give written notice of the suspension or the proposed withdrawal to the director of the laboratory and shall give the director an opportunity to respond. Such action shall become effective upon oral or written notification, whichever is earlier, to the laboratory or manufacturer. If there are conflicts as to any material fact concerning the reason for withdrawal, a hearing may be requested in accordance with the procedure in § 79.4(c)(3) of this chapter. The action under appeal shall continue in effect pending the final determination of the Administrator, unless otherwise ordered by the Administrator. The Administrator's final determination constitutes final agency action.

(d) The Administrator may require approved laboratories to reimburse APHIS for part or all of the costs associated with the approval and monitoring of the laboratory.

(Approved by the Office of Management and Budget under control numbers 0579-0101 and 0579-0469)

12. The heading for subpart B is revised to read as set forth below:

Subpart B—Scrapie Free Flock Certification Program

13. Section 54.21 is revised to read as follows:

§ 54.21 Participation.

Any owner of a sheep or goat flock may apply to enter the Scrapie Free Flock Certification Program by sending a written request to a State scrapie certification board or to the Veterinary Services, Field Operations, AVIC responsible for the State involved. A notice containing a current list of flocks participating in the Scrapie Free Flock Certification Program, and the certification status of each flock, may be obtained from the APHIS website at

<http://www.aphis.usda.gov/animal-health/scrapie>. A list of noncompliant flocks and a list of flocks that sold exposed animals that could not be traced may also be obtained from this site, and these lists may be obtained by writing to the National Scrapie Program Coordinator, Strategy and Policy, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737-1235.

(Approved by the Office of Management and Budget under control number 0579-0101)

PART 79--SCRAPIE IN SHEEP AND GOATS

14. The authority citation for part 79 continues to read as follows:

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

15. Section 79.1 is amended as follows:

- a. By revising the definition for *Animal identification number (AIN)*;
- b. In the definition for *Breed association and registries*, by removing the words “listed in § 151.9 of this chapter”;
- c. By removing the definition for *Certificate*;
- d. By adding in alphabetical order a definition for *Classification or reclassification investigation*;
- e. By revising the definitions for *Consistent State*, *Exposed animal*, and *Exposed flock*;
- f. By adding in alphabetical order a definition for *Flock identification (ID) number*;
- g. In the definition for *Flock plan*, by removing the citation “§ 54.8(a)(f)” and by adding the words “§ 54.8(a) through (j)” in its place;
- h. By adding in alphabetical order definitions for *Flock under investigation*, *Genetically less susceptible exposed sheep*, *Genetically resistant exposed sheep*, *Genetically resistant sheep*, *Genetically susceptible animal*, *Genetically susceptible exposed animal*, *Group/lot identification number (GIN)*;

- i. By revising the definition for *High-risk animal*;
- j. By adding in alphabetical order definitions for *Interstate certificate of veterinary inspection (ICVI)* and *Low-risk commercial flock*;
- k. By removing the definition for *Low-risk commercial sheep*;
- l. By adding in alphabetical order a definition for *Low-risk exposed animal*;
- m. By removing the definition for *Low-risk goat*;
- n. By adding in alphabetical order a definition for *National Uniform Eartagging System (NUES)*;
- o. In the definition for *Noncompliant flock*, in paragraph (3), by removing the words “owner statement” and adding the words “owner/hauler statement” in their place;
- p. By revising the definitions for *Official eartag*, *Official genotype test*, and *Official identification device or method*;
- q. By adding in alphabetical order definitions for *Official identification number*, *Officially identified*, and *Owner/hauler statement*;
- r. By removing the definition for *Owner statement*;
- s. By adding in alphabetical order a definition for *Person*;
- t. By revising the definition for *Premises identification number (PIN)*;
- u. By adding in alphabetical order a definition for *Restricted animal sale or restricted livestock facility*;
- v. In the heading of the definition for *Scrapie Flock Certification Program (SFCP)*, by adding the word “Free” immediately after the word “Scrapie”;
- w. In the heading of the definition for *Scrapie Flock Certification Program standards*, by adding the word “Free” immediately following the word “Scrapie” and, in footnote 2, by

removing the internet address “http://www.aphis.usda.gov/vs” and adding the internet address “http://www.aphis.usda.gov/animal-health/scrapie” in its place;

x. In the definition for *Scrapie-positive animal*, in paragraph (2) by adding the words “, and/or ELISA,” immediately after the word “immunohistochemistry” and in paragraph (5) by removing the words “test method” and adding the words “method or combination of methods” in their place;

y. By removing the definition for *Separate contemporary lambing groups*;

z. By revising the definition for *Slaughter channels*;

aa. By revising paragraph (1) of the definition for *Suspect animal*;

bb. By revising the definition for *Terminal feedlot*; and

cc. By adding in alphabetical order a definition for *Test eligible*.

The additions and revisions read as follows:

§ 79.1 Definitions.

* * * * *

Animal identification number (AIN). This term has the meaning set forth in § 86.1 of this subchapter, except that only AIN devices approved and distributed in accordance with § 79.2(k) and methods approved for use in sheep and goats in accordance with § 79.2(a)(2) are included.

* * * * *

Classification or reclassification investigation. An epidemiological investigation conducted or directed by a DSE for the purpose of designating or redesignating the status (e.g., exposed, high-risk, infected, source, suspect, etc.) of a flock or animal. In conducting such an investigation, the DSE will evaluate the available records for flocks and individual animals and conduct or direct any testing needed to assess the status of a flock or animal. The status of an

animal or flock will be determined based on the applicable definitions in this section and, when needed to make a designation under § 79.4, official genotype test results, exposure risk, scrapie type involved, and/or results of official scrapie testing on live or dead animals.

* * * * *

Consistent State. (1) A State that the Administrator has determined conducts an active State scrapie control program that meets the requirements of § 79.6 or effectively enforces a State designed plan that the Administrator determines is at least as effective in controlling scrapie as the requirements of § 79.6.

(2) A list of Consistent States can be found on the internet at <http://www.aphis.usda.gov/animal-health/scrapie>.

* * * * *

Exposed animal. Any animal or embryo that:

- (1) Has been in a flock with a scrapie-positive female animal;
- (2) Has been in an enclosure with a scrapie-positive female animal at any location;
- (3) Resides in a noncompliant flock; or

(4) Has resided on the premises of a flock before or while it was designated an infected or source flock and before a flock plan was completed. An animal shall not be designated an exposed animal if it only resided on the premises before the date that infection was most likely introduced to the premises as determined by a Federal or State representative. If the probable date of infection cannot be determined based on the epidemiologic investigation, a date 2 years before the birth of the oldest scrapie-positive animal born in that flock will be used. If the actual birth date is unknown, the date of birth will be estimated based on examination of the teeth and any available records. If an age estimate cannot be made, the animal will be assumed to have

been 48 months of age on the date samples were collected for scrapie diagnosis. Exposed animals will be further designated as genetically resistant exposed sheep, genetically less susceptible exposed sheep, genetically susceptible exposed animals, or low-risk exposed animals. An animal will no longer be an exposed animal if it is redesignated in accordance with § 79.4.

Exposed flock. (1) Any flock that was designated an infected or source flock that has completed a flock plan and that retained a female genetically susceptible exposed animal;

(2) Any flock under investigation that retains a female genetically susceptible exposed animal or a suspect animal, or whose owner declines to complete genotyping and live-animal and/or post-mortem scrapie testing required by the APHIS or State representative investigating the flock; or

(3) Any noncompliant flock or any flock for which a PEMMP is required that is not in compliance with the conditions of the PEMMP. A flock will no longer be an exposed flock if it is redesignated in accordance with § 79.4.

* * * * *

Flock identification (ID) number. A nationally unique number assigned by a State, federally recognized Tribal or Federal animal health authority to a group of animals that are managed as a unit on one or more premises and are under the same ownership. The flock ID number must begin with the State postal abbreviation or APHIS-assigned Tribal code, must have no more than nine alphanumeric characters, and must not contain the characters "I", "O", or "Q" other than as part of the State postal abbreviation or another standardized format authorized by the administrator and recorded in the National Scrapie Database. APHIS may assign Tribal codes to any federally recognized Tribe that maintains sheep or goats on Tribal lands. The flock

ID number must be recorded in and linked to one or more PINs or LIDs in the National Scrapie Database.

* * * * *

Flock under investigation. Any flock in which an APHIS or State representative has determined that a scrapie suspect animal, high-risk animal, or scrapie-positive animal resides or may have resided. A flock will no longer be a flock under investigation if it is redesignated in accordance with § 79.4.

Genetically less susceptible exposed sheep. Any sheep or sheep embryo that is:

(1) An exposed sheep or sheep embryo of genotype AA QR, unless the Administrator determines that it is epidemiologically linked to a scrapie-positive RR or AA QR sheep or to a scrapie type to which AA QR sheep are not less susceptible; or

(2) An exposed sheep or sheep embryo of genotype AV QR, unless the Administrator determines that it is epidemiologically linked to a scrapie-positive RR or QR sheep, to a flock that the Administrator has determined may be affected by valine-associated scrapie (based on an evaluation of the genotypes of the scrapie-positive animals linked to the flock), or to another scrapie type to which the Administrator has determined AV QR sheep are not less susceptible; or

(3) An exposed sheep or sheep embryo of a genotype that has been exposed to a scrapie type to which the Administrator has determined that genotype is less susceptible.

(4) NOTE: In this definition R refers to codon 171 and A refers to codon 136, and Q represents any genotype other than R at codon 171 and V represents any genotype other than A at codon 136.

Genetically resistant exposed sheep. Any exposed sheep or sheep embryo of genotype RR at codon 171 unless the Administrator determines that it is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type to which RR sheep are not resistant.

Genetically resistant sheep. Any sheep or sheep embryo of genotype RR at codon 171 unless it is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type that affects RR at codon 171 sheep.

Genetically susceptible animal. Any goat or goat embryo, sheep or sheep embryo of a genotype other than RR or QR, where Q represents any genotype other than R at codon 171 or sheep or sheep embryo of undetermined genotype.

Genetically susceptible exposed animal. Excluding low-risk exposed animals, any exposed animal or embryo that is also:

- (1) A genetically susceptible animal; or
- (2) A sheep or sheep embryo of genotype AV QR that the Administrator has determined is epidemiologically linked to a scrapie-positive RR or QR sheep, to a flock that the Administrator has determined may be affected by valine-associated scrapie (based on an evaluation of the genotypes of the scrapie-positive animals linked to the flock), or to a scrapie type to which AV QR sheep are susceptible; or
- (3) A sheep or sheep embryo of genotype AA QR that the Administrator has determined is epidemiologically linked to a scrapie-positive RR or AA QR sheep or to a scrapie type to which AA QR sheep are susceptible; or
- (4) A sheep or sheep embryo of genotype RR that the Administrator has determined is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type to which RR sheep are susceptible.

(5) NOTE: In this definition, R refers to codon 171 and A refers to codon 136, and Q represents any genotype other than R at codon 171 and V represents any genotype other than A at codon 136.

Group/lot identification number (GIN). The identification number used to uniquely identify a unit of animals that is managed together as one group. The format of the GIN may be either as defined in § 86.1 of this chapter, or the flock identification number followed by a six-digit representation of the date on which the group or lot of animals was assembled (MM/DD/YY). If more than one group is created on the same date a sequential number will be added to the end of the GIN. A group lot comprised of animals from a single flock of origin may be subdivided after leaving the premises on which the group lot was formed by adding an S followed by a sequential number to the end of the GIN to create a GIN for each sub group. If a flock identification number is used, the flock identification number, date, and sequential number(s) will be separated by hyphens.

High-risk animal. The female offspring or embryo of a scrapie-positive female animal, or any suspect animal, or a female genetically susceptible exposed animal, or any exposed animal that the Administrator determines to be a potential risk. The Administrator may base the determination that an exposed animal poses a potential risk on the scrapie type, the epidemiology of the flock or flocks with which it is epidemiologically linked, including genetics of the positive sheep, the prevalence of scrapie in the flock, any history of recurrent infection, and other animal or flock characteristics. An animal will no longer be a high-risk animal if it is redesignated in accordance with § 79.4.

* * * * *

Interstate certificate of veterinary inspection (ICVI). An official document issued by a Federal, State, Tribal, or accredited veterinarian certifying the inspection of animals in preparation for interstate movement or other uses as described in this part and in accordance with § 79.5.

* * * * *

Low-risk commercial flock. A flock composed of commercial whitefaced, whitefaced cross, or commercial hair sheep or commercial goats that were born in, and have resided throughout their lives in, flocks with no known risk factors for scrapie, including any exposure to female blackfaced sheep other than whiteface crosses born on the premises; that has never contained a scrapie-positive female, suspect female, or high-risk animal; and that has never been an infected, exposed, or source flock or a flock under investigation. The animals are identified with a legible permanent brand or ear notch pattern registered with an official brand registry or with an official flock identification eartag. The term “brand” includes official brand registry brands on eartags in those States whose brand law or regulation recognizes brands placed on eartags as official brands. Low-risk commercial flocks may exist only in a State where in the previous 10 years no flock that had met the definition of a low-risk commercial flock prior to a classification investigation was designated a source or infected flock.

Low-risk exposed animal. Any exposed animal to which the Administrator has determined one or more of the following applies:

(1) The positive animal that was the source of exposure was not born in the flock and did not lamb in the flock or in an enclosure where the exposed animal resided;

(2) The Administrator and State representative concur that the animal is unlikely to be infected due to factors such as, but not limited to, where the animal resided or the time period the animal resided in the flock;

(3) The exposed animal is male and was not born in an infected or source flock;

(4) The exposed animal is a castrated male;

(5) The exposed animal is an embryo of a genetically resistant exposed sheep or a genetically less susceptible exposed sheep unless placed in a recipient that was a genetically susceptible exposed animal; or

(6) The animal was exposed to a scrapie type and/or is of a genotype that the Administrator has determined poses low risk of transmission.

* * * * *

National Uniform Eartagging System (NUES). This term has the meaning set forth in § 86.1 of this subchapter.

* * * * *

Official eartag. This term has the meaning set forth in § 86.1 of this subchapter, except that only eartags approved and distributed in accordance with § 79.2(k) are included.

Official genotype test. A test to determine the genotype of a live or dead animal conducted at either the National Veterinary Services Laboratories or at an approved laboratory. The test subject must be an animal that is officially identified and the test accurately recorded on an official form supplied or approved by APHIS, with the samples collected and shipped to the laboratory using a shipping method specified by the laboratory by:

(1) An accredited veterinarian;

(2) A State or APHIS representative; or

(3) The animal's owner or owner's agent, using a tamper-resistant sampling kit approved by APHIS for this purpose.

* * * * *

Official identification device or method. This term has the meaning set forth in § 86.1 of this subchapter, except that only devices approved and distributed in accordance with § 79.2(k) and methods approved for use in sheep and goats in accordance with § 79.2(a)(2) are included.

Official identification number. This term has the meaning set forth in § 86.1 of this subchapter.

Officially identified. Identified by means of an official identification device or method approved by the Administrator for use in sheep and goats in accordance with this part.

* * * * *

Owner/hauler statement. (1) A signed written statement by the owner or hauler that includes:

- (i) The name, address, and phone number of the owner and, if different, the hauler;
- (ii) The date the animals were moved;
- (iii) The flock identification number or PIN assigned to the flock or premises of the animals;
- (iv) If moving individually unidentified animals or other animals required to move with a group/lot identification number, the group/lot identification number and any information required to officially identify the animals;
- (v) The number of animals;
- (vi) The species, breed, and class of animals. If breed is unknown, for sheep the face color and for goats the type (milk, fiber, or meat) must be recorded instead; and

(vii) The name and address of point of origin, if different from the owner's address, and the destination name and address.

(2) An existing document that includes the information required in paragraphs (1)(i) to (vii) of this definition and that is signed by the owner or the hauler may be used as an owner/hauler statement.

* * * * *

Person. An individual, partnership, company, corporation, or any other legal entity.

* * * * *

Premises identification number (PIN). This term has the meaning set forth in § 86.1 of this subchapter. APHIS may also maintain historical and/or State premises numbers and link them to the premises identification number in records and databases. Such secondary or historical numbers are typically the State's two-letter postal abbreviation followed by a number assigned by the State.

Restricted animal sale or restricted livestock facility. A sale where any animals in slaughter channels are maintained separate from other animals not in slaughter channels other than animals from the same flock of origin and are sold in lots that consist entirely of animals sold for slaughter only or a livestock facility at which all animals are in slaughter channels and where the sale or facility manager maintains a copy of, or maintains a record of, the information from, the owner/hauler statement for all animals entering and leaving the sale or facility. A restricted animal sale may be held at a livestock facility that is not restricted.

* * * * *

Slaughter channels. Animals in slaughter channels include any animal that is sold, transferred, or moved either directly to or through a restricted animal sale or restricted livestock

facility to an official slaughter establishment that is under Food Safety and Inspection Service (FSIS) jurisdiction per the Federal Meat Inspection Act (FMIA) or under State inspection that FSIS has recognized as at least equal to Federal inspection or to a custom exempt slaughter establishment as defined by FSIS (9 CFR 303.1) for immediate slaughter or to an individual for immediate slaughter for personal use or to a terminal feedlot.

* * * * *

Suspect animal. * * *

(1) A mature sheep or goat as evidenced by eruption of the first incisor that has been condemned by FSIS or a State inspection authority for central nervous system (CNS) signs, or that exhibits any of the following clinical signs of scrapie and has been determined to be suspicious for scrapie by an accredited veterinarian or a State or USDA representative, based on one or more of the following signs and the severity of the signs: Weakness of any kind including, but not limited to, stumbling, falling down, or having difficulty rising, not including those with visible traumatic injuries and no other signs of scrapie; behavioral abnormalities; significant weight loss despite retention of appetite or in an animal with adequate dentition; increased sensitivity to noise and sudden movement; tremors; star gazing; head pressing; bilateral gait abnormalities such as but not limited to incoordination, ataxia, high stepping gait of forelimbs, bunny-hop movement of rear legs, or swaying of back end, but not including abnormalities involving only one leg or one front and one back leg; repeated intense rubbing with bare areas or damaged wool in similar locations on both sides of the animal's body or, if on the head, both sides of the poll; abraded, rough, thickened, or hyperpigmented areas of skin in areas of wool/hair loss in similar locations on both sides of the animal's body or, if on the head,

both sides of the poll; or other signs of CNS disease. An animal will no longer be a suspect animal if it is redesignated in accordance with § 79.4.

* * * * *

Terminal feedlot. (1) A dry lot approved by a State or APHIS representative or an accredited veterinarian who is authorized by the Administrator to perform this function where animals in the terminal feedlot are separated from all other animals by at least 30 feet at all times or are separated by a solid wall through, over, or under which fluids cannot pass and contact cannot occur and must be cleaned of all organic material prior to being used to contain sheep or goats that are not in slaughter channels, where only castrated males are maintained with female animals and from which animals are moved only to another terminal feedlot or directly to slaughter; or

(2) A dry lot approved by a State or APHIS representative or an accredited veterinarian authorized by the Administrator to perform this function where only animals that either are not pregnant based on the animal being male, an owner certification that any female animals have not been exposed to a male in the preceding 6 months, an ICVI issued by an accredited veterinarian stating the animals are not pregnant, or the animals are under 6 months of age at time of receipt, where only castrated males are maintained with female animals, and all animals in the terminal feedlot are separated from all other animals such that physical contact cannot occur including through a fence and from which animals are moved only to another terminal feedlot or directly to slaughter; or

(3) A pasture when approved by and maintained under the supervision of the State and in which only nonpregnant animals are permitted based on the animal being male, an owner certification that any female animals have not been exposed to a male in the preceding 6 months,

or an ICVI issued by an accredited veterinarian stating the animals are not pregnant, or the animals are under 6 months of age at time of receipt, where only castrated males are maintained with female animals, where there is no direct fence-to-fence contact with another flock, and from which animals are moved only to another terminal feedlot or directly to slaughter.

(4) Records of all animals entering and leaving a terminal feedlot must be maintained for 5 years after the animal leaves the feedlot and must meet the requirements of § 79.2, including either a copy of the required owner/hauler statements for animals entering and leaving the facility or the information required to be on the statements. Records must be made available for inspection and copying by an APHIS or State representative upon request.

Test eligible. An animal that meets a test protocol's age and post-exposure elapsed time requirements for the test to be meaningfully applied.

* * * * *

16. Section 79.2 is revised to read as follows:

§ 79.2 Identification and records requirements for sheep and goats in interstate commerce.

(a) No sheep or goat that is required to be individually identified or group identified by § 79.3 may be sold, disposed of, acquired, exhibited, transported, received for transportation, offered for sale or transportation, loaded, unloaded, or otherwise handled in interstate commerce or commingled with such animals or be loaded or unloaded at a premises or animal concentration point (including premises that exhibit animals) where animals are received that have been in interstate commerce or from which animals are moved in interstate commerce unless each sheep or goat has been identified in accordance with this section.

(1) The sheep or goat must be identified to its flock of origin and to its flock of birth⁴ by the owner of the animal or his or her agent, at whichever of the following points in interstate commerce comes first:

(i) Prior to the point of first commingling of the sheep or goats with sheep or goats from any other flock of origin;

(ii) Upon unloading of the sheep or goats at a livestock facility approved in accordance with § 71.20 of this subchapter and that has agreed to act as an agent for the owner to apply official identification and prior to commingling with animals from another flock of origin. Such facilities may identify animals after sale if the facility maintains unidentified animals from different flocks of origin or, when required, different flocks of birth in separate enclosures until officially identified. The animals must be accompanied by an owner/hauler statement that contains the information needed for the livestock facility to officially identify the animals to their flock of origin and, when required, their flock of birth;

(iii) Upon transfer of ownership of the sheep or goats;

(iv) If the owner of the premises or the owner of the animal engages in the interstate commerce of animals, then prior to moving a sheep or goat from the premises on which it resides, unless the animals are moving to a livestock facility approved to handle the species and class of animal to be moved as described in § 71.20 of this subchapter that has agreed to act as an agent for the owner to apply official identification and in accordance with paragraph (a)(1)(ii) of

⁴ You need not identify an animal to its flock of birth or its flock of origin if this information is unknown because the animal changed ownership while it was exempted from flock of origin identification requirements in accordance with § 79.6(a)(10)(i). Such animals may be moved interstate with individual animal identification that is only traceable to the State of origin and to the owner of the animals at the time they were so identified. To use this exemption the person applying the identification must have supporting documentation indicating that the animals were born and had resided throughout their life in the State.

this section or to a slaughter plant listed in accordance with § 71.21 of this subchapter as part of a group lot. Unless prohibited by State law or regulation, this does not preclude a person from moving animals as part of a group lot directly to another site in the same State to have official eartags that have been assigned to the animal's flock of origin in the National Scrapie Database applied to the animals;

(v) In the case of animals that have only resided on premises and in flocks owned by persons that do not engage in interstate commerce, upon unloading a sheep or goat at a livestock facility or other premises where animals are received that have been in interstate commerce or from which animals are moved in interstate commerce and prior to commingling with animals from another flock of origin. Such animals must be accompanied by an owner/hauler statement that contains the information needed to officially identify the animals to their flock of origin and, when required, their flock of birth; or

(vi) Before moving a sheep or goat across a State line, unless moving to an approved livestock facility that is approved to handle that species and class of animals as described in § 71.20 of this subchapter that has agreed to act as an agent for the owner to apply official identification, and prior to commingling with animals from another flock of origin. Such animals must be accompanied by an owner/hauler statement that contains the information needed for the livestock facility to officially identify the animals to their flock of origin and, when required, their flock of birth.

(2) The sheep or goats must be identified and remain identified using a device or method approved in accordance with paragraph (k) of this section. All animals required to be individually identified by § 79.3 shall be identified with official identification devices or methods. A list of approved identification devices and methods, including restrictions on their

use, is available at <http://www.aphis.usda.gov/animal-health/scrapie>. Written requests for approval of sheep or goat identification device types or methods not listed at <http://www.aphis.usda.gov/animal-health/scrapie> should be sent to the National Scrapie Program Coordinator, Strategy and Policy, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737-1235. If the Administrator determines that an identification device or method will provide an effective means of tracing sheep and goats in interstate commerce, APHIS will provide public notice that the device type or method, along with any restrictions on its use, has been added to the list of approved devices and methods of official sheep and goat identification.

(3) No person shall buy or sell, for his or her own account or as the agent of the buyer or seller, transport, receive for transportation, offer for sale or transportation, load, unload, or otherwise handle any animal that is in or has been in interstate commerce that has not been identified as required by this section including loading or unloading at a premises (including premises that exhibit animals) where animals are received that have been in interstate commerce or from which animals are moved in interstate commerce. No person shall commingle animals with any animal that is in or has been in interstate commerce that has not been identified as required by this section. If the person transporting animals is aware of any animal in the shipment that loses its identification to its flock of origin while in interstate commerce, the person transporting the animal is required to inform the receiving party of this fact, and it is the responsibility of the person who has control or possession of the animal upon unloading/delivery to identify the animal or have the animal identified prior to commingling it with any other animals. This shall be done by applying individual animal identification to the animal as required in paragraph (a)(2) of this section and recording the means of identification and the corresponding animal identification number on the waybill or other shipping document. If the

flock of origin cannot be determined, all possible flocks of origin shall be listed on the record, or if this cannot be done, the animal must be identified with a slaughter only eartag and may only move in slaughter channels or, in the case of sheep, may be officially identified and moved for other purposes if the animal is inspected by an accredited veterinarian, found free of evidence of infectious or contagious disease and officially genotyped as AA QR or AA RR.

(b) The State Animal Health Official or Veterinary Services, Field Operations, Area Veterinarian in Charge (AVIC) responsible for the State involved, whoever is responsible for issuing official identification devices or numbers in that State and for assigning flock identification numbers and premises identification numbers in that State in the National Scrapie Database, may issue sets of unique serial numbers or flock identification/production numbers for use on official individual identification devices (such as eartags or tattoos). Flock identification/production numbers may only be assigned to owners of breeding flocks.

(1) *Animals not in slaughter channels.* Official identification numbers for use on animals not in slaughter channels may only be assigned either directly to the owner of a breeding flock for application to animals that originated in a breeding flock owned by them or, in the case of official serial numbers or serial number devices, to APHIS or State representatives or accredited veterinarians or other responsible individuals as described in paragraphs (b)(2) and (3) of this section. APHIS or State representatives may apply official identification to animals or issue official identification to owners of breeding flocks for application to animals in those flocks. APHIS and State personnel who apply or issue official identification must provide to APHIS, in a manner acceptable to APHIS, assignment data associating the serial numbers applied to animals or issued to owners, to the flock of origin and, when required, the flock of birth. Accredited veterinarians who apply official serial numbers or devices when requested by

APHIS must provide to APHIS, in a manner acceptable to APHIS, assignment data associating the serial sequences applied to animals to the flock of origin and, when required, the flock of birth. One such method would be to enter the data into the National Scrapie Database. Such requests may be made directly to a person or persons or to accredited veterinarians as a group through amendment of the Scrapie Program Standards Volume 1: National Scrapie Eradication Program.

(2) *Assignment of serial numbers.* The official responsible for issuing eartags in a State may also assign serial numbers of official eartags to other responsible persons, such as 4-H leaders, if the State Animal Health Official and Veterinary Services, Field Operations, AVIC responsible for the State involved agree that such assignments will improve scrapie control and eradication within the State. Such persons assigned serial numbers may either directly apply eartags to animals, or may reassign eartag numbers to producers. Such persons must maintain appropriate records in accordance with paragraph (g) of this section that permit traceback of animals to their flock of origin, or flock of birth when required, and must either reassign the tags in the National Scrapie Database or, if permitted by the Veterinary Services, Field Operations, AVIC responsible for the State involved, provide a written record of the reassignment to the Field Office or the State Office for entry into the National Scrapie Database.

(3) *Persons handling sheep and goats in commerce.* Sets of unique individual identification serial numbers may be assigned to persons who handle sheep and goats, that did not originate in a breeding flock owned by them, if they apply to and are approved by the State Animal Health Official or the Veterinary Services, Field Operations, AVIC responsible for the State in which the person maintains his or her business location, whichever is responsible for issuing official identification devices or numbers in that State and for assigning flock

identification numbers and premises identification numbers in that State in the National Scrapie Database. When requested by APHIS, persons who apply official identification to sheep or goats that did not originate in a breeding flock owned by them must provide, in a manner acceptable to APHIS, assignment data associating assigned serial sequences to the flock of origin and, when required, the flock of birth. One such method would be to enter the data into the National Scrapie Database. The request may be made directly to a person or persons or to a class of persons through amendment of the Scrapie Program Standards Volume 1: National Scrapie Eradication Program. The State Animal Health Official or the Administrator may limit the assignment of official identification devices or numbers to persons, or classes of persons, for use on animals that did not originate in a breeding flock owned by them to slaughter only devices or numbers.

(4) *Breed registries.* Sets of unique individual identification numbers may also be assigned by the Administrator to breed registries that agree to reassign the sequences to the flock of origin and, and when required, the flock of birth and to provide associated registry identifiers such as registry tattoo numbers to APHIS in the National Scrapie Database.

(5) *Noncompliance.* In addition to any applicable criminal or civil penalties any person who fails to comply with the requirements of this section or that makes false statements in order to acquire official identification numbers or devices shall not be assigned official identification numbers or official identification devices for a period of at least 1 year. If a person who is not in compliance with these requirements has already been assigned such numbers, the Administrator may withdraw the assignment by giving notice to such person. Such withdrawal or failure to assign official identification numbers may be appealed in accordance with § 79.4(c)(3). A

person shall be subject to criminal and civil penalties if he or she continues to use assigned numbers that have been withdrawn from his or her use.

(c) No person shall apply a premises or flock identification number or a brand or ear notch pattern to an animal that did not originate on the premises or flock to which the number was assigned by a State or APHIS representative or to which the brand or ear notch pattern has been assigned by an official brand registry. This includes individual identification such as USDA eartags that have been assigned to a premises or flock and registration tattoos that contain prefixes that have been assigned to a premises or flock for use as premises or flock identification. Unless the number sequence was issued specifically for use on animals born in a flock, this would not preclude the owner of a flock from using an official premises or flock identification number tag assigned to that flock on an animal owned by him or her that resides in that flock but that was born or previously resided on a different premises as long as the records required in paragraph (g) of this section are maintained.

(d) No person shall sell or transfer an official identification device or number assigned to his or her premises or flock except when it is transferred with a sheep or goat to which it has been applied as official identification or as directed in writing by an APHIS or State representative.

(e) No person shall use an official identification device or number provided for the identification of sheep and goats other than for the identification of a sheep or goat.

(f) Persons who engage in the interstate commerce of animals including persons that handle or own animals that have been in interstate commerce or that purchase, acquire, sell, or dispose of sheep and/or goats from or to persons who engage in the interstate commerce of animals, whether or not the animals are required to be officially identified, must maintain

business records (such as yarding receipts, sale tickets, invoices, and waybills) for 5 years.

These persons must make the records available for inspection and copying by any authorized USDA or State representative upon that representative's request and presentation of his or her official credentials. The records must include the following information:

- (1) The number of animals purchased or sold (or transferred without sale);
 - (2) The date of purchase, sale, or other transfer;
 - (3) The name and address of the person from whom the animals were purchased or otherwise acquired or to whom they were sold or otherwise transferred;
 - (4) The species, breed, and class of animal. If breed is unknown, for sheep the face color and for goats the type (milk, fiber, or meat) must be recorded instead;
 - (5) A copy of the brand inspection certificate for animals officially identified with brands or ear notches;
 - (6) A copy of any certificate or owner/hauler statement required for movement of the animals purchased, sold, or otherwise transferred; and
 - (7) If the flock of origin or the receiving flock is under a flock plan or post-exposure management and monitoring plan, any additional records required by the plan.
- (g) Persons who apply official individual or group/lot identification to animals must maintain records for 5 years. These persons must make the records available for inspection and copying by any authorized USDA or State representative upon that representative's request and presentation of his or her official credentials. The records must include the following information:

(1) The flock identification number of the flock of origin, the name and address of the person who currently owns the animals, and the name and address of the owner of the flock of origin if different;

(2) The name and address of the owner of the flock of birth, if known, for animals in another flock and not already identified to flock of birth;

(3) The date the animals were officially identified;

(4) The number of sheep and the number of goats identified;

(5) The breed and class of the animals. If breed is unknown, for sheep the face color and for goats the type (milk, fiber, or meat) must be recorded instead;

(6) The official identification numbers applied to animals by species or the GIN applied in the case of a group lot;

(7) Whether the animals were identified with “Slaughter Only” or “Meat” identification devices; and

(8) Any GIN with which the animal was previously identified.

(h) Official identification devices are intended to provide permanent identification of livestock and to ensure the ability to find the source of animal disease outbreaks. Removal of these devices, including devices applied to imported animals in their countries of origin and recognized by the Administrator as official, is prohibited except at the time of slaughter, at any other location upon the death of the animal, or as otherwise approved by the State or Tribal animal health official or the Veterinary Services, Field Operations, AVIC responsible for the State involved when a device needs to be replaced.

(1) All man-made identification devices affixed to sheep or goats moved interstate must be removed at slaughter and correlated with the carcasses through final inspection by means

approved by the Food Safety and Inspection Service (FSIS). If diagnostic samples, including whole heads, are taken, the identification devices must be packaged with the samples and must be left attached to approximately 1 inch of tissue or to the whole head to allow for identity testing and be correlated with the carcasses through final inspection by means approved by FSIS. Devices collected at slaughter must be made available to APHIS and FSIS.

(2) All official identification devices affixed to sheep or goat carcasses moved interstate for rendering must be removed at the rendering facility and made available to APHIS. If diagnostic samples, including whole heads, are taken, the identification devices must be packaged with the samples and must be left attached to approximately 1 inch of tissue or to the whole head to allow for identity testing.

(3) If a sheep or goat loses an official identification device except while in interstate commerce as described in paragraph (a)(3) of this section and needs a new one, the person applying the new official identification device must record the official identification number from the old device, if known, in addition to the information required to be recorded in accordance with paragraph (g) of this section.

(i) Replacement of official identification devices for reasons other than loss include:

(1) Circumstances under which a State or Tribal animal health official or the Veterinary Services, Field Operations, AVIC responsible for the State involved may authorize replacement of an official identification device include, but are not limited to:

(i) Deterioration of the device such that loss of the device appears likely or the number can no longer be read;

(ii) Infection at the site where the device is attached, necessitating application of a device at another location (e.g., a slightly different location of an eartag in the ear);

(iii) Malfunction of the electronic component of a radio frequency identification (RFID) device; or

(iv) Incompatibility or inoperability of the electronic component of an RFID device with the management system or unacceptable functionality of the management system due to use of an RFID device.

(2) Any time an official identification device is replaced, as authorized by the State or Tribal animal health official or the Veterinary Services, Field Operations, AVIC responsible for the State involved, the person replacing the device must record the following information about the event and maintain the record for 5 years:

(i) The date when the device was removed;

(ii) The address of the location and the name, phone number and email address of the person responsible for the location where the device was removed;

(iii) The official identification number (to the extent possible) on the device removed;

(iv) The type of device removed (e.g., metal eartag, RFID eartag);

(v) The reason for the removal of the device;

(vi) The new official identification number on the replacement device; and

(vii) The type of replacement device applied.

(j) Beginning on [Insert date 30 days after date of publication in the Federal Register], no more than one official eartag may be applied to an animal; except that:

(1) Another official eartag may be applied providing it bears the same official identification number as an existing one.

(2) In specific cases when the need to maintain the identity of an animal is intensified (e.g., such as for export shipments, quarantined herds, field trials, experiments, or disease

surveys), a State or Tribal animal health official or the Veterinary Services, Field Operations, AVIC responsible for the State involved may approve the application of a second official eartag. The person applying the second official eartag must record the following information about the event and maintain the record for 5 years: The date the second official eartag is added; the reason for the additional official eartag device; and the official identification numbers of both official eartags.

(3) An eartag with an animal identification number (AIN) beginning with the 840 prefix (either radio frequency identification or visual-only tag) may be applied to an animal that is already officially identified with another eartag. The person applying the AIN eartag must record the date the AIN tag is added and the official identification numbers of all official eartags on the animal and must maintain those records for 5 years.

(4) An official eartag that utilizes a flock identification number may be applied to a sheep or goat that is already officially identified with an official eartag if the animal has resided in the flock to which the flock identification number is assigned.

(k) Requirements for approval of official identification devices include:

(1) The Administrator may approve companies to produce official identification devices for use on sheep or goats. Devices may be plastic, metal, or other suitable materials and must be an appropriate size for use in sheep and goats. Devices must be able to legibly accommodate the required alphanumeric sequences. Devices must resist removal and be difficult to place on another animal once removed unless the construction of the device makes such tampering evident, but need not be tamper-proof. Devices must be readily distinguishable as USDA official sheep and goat identification devices; must carry the alphanumeric sequences, symbols, or logos specified by APHIS; must be an allowed color for the intended use, and must have a means of

discouraging counterfeiting, such as use of a unique copyrighted logo or trade mark. Devices for use only on animals in slaughter channels must be medium blue and marked with the words “Meat” or “Slaughter Only”. Devices that use RFID must conform to ISO 11784 and ISO 11785 standards unless otherwise approved. The Administrator may specify the color, shape or size of a device for an intended use to make them readily identifiable.

(2) Written requests for approval of official identification devices for sheep and goats should be sent to the National Scrapie Program Coordinator, Strategy and Policy, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737-1235. The request must include:

(i) The materials used in the device and in the case of RFID the transponder type and data regarding the lifespan and read range.

(ii) Any available data regarding the durability of the device, durability and legibility of the identification numbers, rate of adverse reactions such as ear infections, and retention rates of the devices in animals, preferably sheep and/or goats.

(iii) A signed statement agreeing to:

(A) Send official identification devices only to a State or APHIS representative, to the owner of a premises or to the contact person for a premises at the address listed in the National Scrapie Database, or as directed by APHIS;

(B) When requested by APHIS, provide a report by State of all tags produced, including the tag sequences produced and the name and address of the person to whom the tags were shipped, and provide supplemental reports of this information when requested by APHIS;

(C) Maintain the security and confidentiality of all tag recipient information acquired as a result of being an approved tag manufacturer and utilize the information only to provide official identification tags; and

(D) Enter the sequences of tags shipped in the National Scrapie Database through an internet webpage interface or other means specified by APHIS prior to shipping the identification device.

(iv) Twenty-five sample devices. Additional tags must be submitted if requested by APHIS.

(3) Approval will only be given for devices for which data have been provided supporting high legibility, readability (visual and RFID), and retention rates in sheep and goats that minimize injury throughout their lifespan, or for which there is a reasonable expectation of such performance. Approval to produce official identification devices will be valid for 1 year and must be renewed annually. The Administrator may grant provisional approval to produce devices for periods of less than 1 year in cases where there is limited or incomplete data. The Administrator may decline to renew a company's approval or suspend or withdraw approval if the devices do not show adequate retention and durability or cause injury in field use or if any of the requirements of this section are not met by the tag company. Companies shall be given 60 days' written notice of intent to withdraw approval. Any person who is approved to produce official identification tags in accordance with this section and who knowingly produces tags that are not in compliance with the requirements of this section, and any person who is not approved to produce such tags but does so, shall be subject to such civil penalties and such criminal liabilities as are provided by 18 U.S.C. 1001, 7 U.S.C. 8313, or other applicable Federal statutes. Such action may be in addition to, or in lieu of, withdrawal of approval to produce tags.

(Approved by the Office of Management and Budget under control numbers 0579-0101 and 0579-0469)

17. Section 79.3 is revised to read as follows:

§ 79.3 General restrictions.

The following prohibitions and movement conditions apply to the movement of or commingling with sheep and goats in interstate commerce, and no sheep or goat may be sold, disposed of, acquired, exhibited, transported, received for transportation, offered for sale or transportation, loaded, unloaded, or otherwise handled in interstate commerce, or commingled with such animals, or be loaded or unloaded at a premises or animal concentration point (including premises that exhibit animals) where animals are received that have been in interstate commerce or from which animals are moved in interstate commerce except in compliance with this part.

(a) No sexually intact animal of any age or castrated animal 18 months of age and older (as evidenced by the eruption of the second incisor) may be moved or commingled with animals in interstate commerce unless it is individually identified to its flock of birth⁵ and is accompanied by an ICVI, except that an ICVI is not required unless the animal is moved across a State line, and except for the following, which may move with group lot identification and an owner/hauler statement:

(1) Animals in slaughter channels that are under 18 months of age (as evidenced by the eruption of the second incisor);

(2) Animals in slaughter channels at 18 months and older (as evidenced by the eruption of the second incisor) if the animals were kept as a group on the same premises on which they

⁵ You need not identify an animal to its flock of birth or its flock of origin if this information is unknown because the animal changed ownership while it was exempted from flock of origin identification requirements in accordance with § 79.6(a)(10)(i). Such animals may be moved interstate with individual animal identification that is only traceable to the State of origin and to the owner of the animals at the time they were so identified. To use this exemption the person applying the identification must have supporting documentation indicating that the animals were born and had resided throughout their life in the State.

were born and have not been maintained in the same enclosure with unidentified animals from another flock at any time, including throughout the feeding, marketing, and slaughter process;

(3) An owner/hauler statement may be used instead of an ICVI for mixed source animals in slaughter channels 18 months of age and older (as evidenced by the eruption of the second incisor) that are identified with official individual identification or in the case of animals from flocks that are low-risk commercial flocks that are identified using identification methods or devices approved for this purpose;

(4) Animals moving for grazing or other management purposes between two premises both owned or leased by the flock owner and recorded in the National Scrapie Database as additional flock premises and where commingling will not occur with unidentified animals that were born in another flock or any animal that is not part of the flock. A request to APHIS to enter additional flock premises in the National Scrapie Database is required before animals are first moved to the premises. Notification is not required for each subsequent movement of animals to that premises. Neither group lot ID nor an owner/hauler statement is required for movements of a flock or its members for flock management purposes within a contiguous premises spanning two or more States. This provision does not include the transiting or sale of animals through such a premises in circumvention of the other requirements of this part; and

(5) Animals moving to a livestock facility approved in accordance with § 71.20 of this subchapter and that has agreed to act as an agent for the owner to apply official identification if the animals have been in the same flock in which they were born and have not been maintained in the same enclosure with unidentified animals born in another flock at any time. Such facilities may identify animals after sale if the facility maintains unidentified animals from different flocks of origin or when required birth in separate enclosures until officially identified.

(b) No scrapie-positive or suspect animal may be moved other than by permit to an APHIS approved research or quarantine facility or for destruction under APHIS or State supervision. Such animals must be individually identified and listed on the permit.

(c) No indemnified high-risk animal or indemnified sexually intact genetically susceptible exposed animal may be moved other than by permit to an APHIS approved research or quarantine facility or for destruction at another site. Such animals that are not indemnified and are not scrapie-positive or suspect animals may be moved to slaughter under permit. Animals moved in accordance with this paragraph must be individually identified and listed on the permit.

(d) No exposed animal may be moved unless it is officially individually identified.

(e) No animal may be moved from an infected flock or source flock except as allowed by an approved flock plan.

(f) No animal may be moved from an exposed flock, a flock under investigation or a flock subject to a PEMMP except as allowed in a PEMMP or where a PEMMP is not required, as allowed by written instructions from an APHIS or State representative.

(g) Animals moved to slaughter:

(1) Once an animal enters slaughter channels the animal may not be removed from slaughter channels. An animal is in slaughter channels if it was sold through a restricted animal sale, resided in a terminal feedlot, was sold with a bill of sale marked for slaughter only, was identified with an identification device or tattoo marked "Slaughter Only" or "MEAT" or was moved in a manner not permitted for other classes of animals. Animals in slaughter channels may move either directly to a slaughter establishment that is under Food Safety and Inspection Service (FSIS) jurisdiction per the Federal Meat Inspection Act (FMIA) or under State

inspection that FSIS has recognized as at least equal to Federal inspection or to a custom exempt slaughter establishment as defined by FSIS (9 CFR 303.1) for immediate slaughter or to an individual for immediate slaughter for personal use or to a terminal feedlot, or may move indirectly to such a destination through a restricted animal sale or restricted livestock facility. Once an animal has entered slaughter channels it may only be officially identified with an official blue eartag marked with the words "Meat" or "Slaughter Only" or an ear tattoo reading "Meat." Animals in slaughter channels must be accompanied by an owner/hauler statement. The statement must also include the name and address of the person or livestock facility from which and where they were acquired, if different from the owner; the slaughter establishment, restricted animal sale, restricted livestock facility or terminal feedlot to which they are being moved, and a statement that the animals are in slaughter channels. A copy of the owner/hauler statement must be provided to the slaughter establishment, restricted animal sale, restricted livestock facility or terminal feedlot to which the animals are moved. Any bill of sale regarding the animals must indicate that the animals were sold for slaughter only.

(2) Animals that were in slaughter channels before arriving at a sale and animals that cannot meet the ID and ICVI requirements for unrestricted movement prior to leaving a sale may not be sold at an unrestricted sale. This does not preclude animals sold at an unrestricted sale from being moved in slaughter channels after sale if identified as required for animals in slaughter channels.

(3) Animals in slaughter channels may not be held in the same enclosure with sexually intact animals from another flock of origin that are not in slaughter channels.

(h) No animals designated for testing as part of a classification or reclassification investigation may be moved until testing is completed and results reported, except for movement

by permit for testing, slaughter, research, or destruction. Such animals must be individually identified and listed on the permit.

(i) The following animals, if not restricted as part of a flock plan or PEMMP, may be moved to any destination without further restriction after being officially identified and designated or redesignated by a DSE to be:

- (1) Genetically resistant exposed sheep;
- (2) Genetically less susceptible exposed sheep; or
- (3) Low-risk exposed animals.

(j) Animals moved from Inconsistent States must meet the following requirements in addition to other requirements of this section.

(1) Sheep and goats not in slaughter channels must be enrolled in the Scrapie Free Flock Certification Program or an equivalent APHIS recognized program or be sheep that are officially genotyped and determined to be AA QR or AA RR, be officially identified, and be accompanied by an ICVI that also states the individual animal identification numbers, the flock of origin, and the flock of birth, if different.

(2) Animals in slaughter channels must be officially identified with an official blue eartag marked with the words "Meat" or "Slaughter Only" and may move only directly to slaughter or to a terminal feedlot. Animals 18 months of age and older (as evidenced by the eruption of the second incisor) in slaughter channels must also be accompanied by an ICVI that states the individual animal identification numbers, and the flock of birth (and the flock of origin, if different).

(k) APHIS may enter into compliance agreements with persons such as dealers and owners of slaughter establishments and markets whereby animals may be received unidentified

or without a required owner/hauler statement even if they cannot be identified to their flock of birth or origin because they were moved or commingled while unidentified, in violation of this part or a State requirement as provided by § 79.6. *Provided that*, the agreement requires the person signing the agreement to report the violation to the Veterinary Services, Field Operations, AVIC responsible for the State involved so that corrective action can be taken against the principal violator. In such cases the animal must be identified with a slaughter only tag, and is moved only in slaughter channels or, in the case of sheep, moved for other purposes if the animal is inspected by an accredited veterinarian, found free of evidence of infectious or contagious disease, and officially genotyped as AA QR or AA RR where Q and R refer to codon 171 and A refers to codon 136. APHIS may also enter into compliance agreements with persons or in the case of approved livestock facilities may amend an approved livestock facility agreement to establish alternative methods to maintain the traceability of animals in slaughter channels to their flock of origin or waive the requirement for individual official identification of animals in slaughter channels if adequate surveillance has been conducted on the flock of origin or an alternative plan is in place to conduct surveillance on animals from the flock of origin when the Administrator and the State Animal Health Official agree that the application of an allowed official identification device or method is unsuitable for a specific circumstance. An example of a specific circumstance could be large unruly horned male goats moving through approved livestock facilities.

(Approved by the Office of Management and Budget under control numbers 0579-0101 and 0579-0469)

18. Section 79.4 is revised to read as follows:

§ 79.4 Designation of scrapie-positive animals, high-risk animals, exposed animals, suspect animals, exposed flocks, infected flocks, noncompliant flocks, and source flocks; notice to owners.

(a) *Designation.* Based on a classification investigation as defined in § 79.1, including testing of animals, if needed, a designated scrapie epidemiologist will designate a flock to be an exposed flock, an infected flock, a source flock, a flock under investigation, and/or a non-compliant flock, or designate an animal to be a scrapie-positive animal, high-risk animal, exposed animal, genetically susceptible exposed animal, genetically resistant exposed sheep, genetically less susceptible exposed sheep, low-risk exposed animal, and/or a suspect animal after determining that the flock or animal meets the criteria of the relevant definition in § 79.1.

(b) *Redesignation.* A reclassification investigation as defined in § 79.1 may be conducted to determine whether the current designated status of a flock or animal may be changed or removed. Reclassification investigations will be initiated and conducted, and redesignation decisions will be made, in accordance with procedures approved by the Administrator. These procedures are available at <http://www.aphis.usda.gov/animal-health/scrapie>.

(c) *Testing and notification procedures.* Any animal that may be a high-risk animal, any animal that may have been exposed to the lambing of a high-risk animal, any suspect animal, and any animal that was born in the flock after a high-risk animal may have lambed may be selected for testing by the DSE or an APHIS or State representative working under the direction of a DSE or the Administrator. Which animals are selected and the method of testing selected animals will be based on the risk associated with the flock and the type and number of animals available for test. When flock records are adequate to determine that all high-risk animals that lambed in the

flock are available for testing, the testing may be limited to postmortem testing of all high-risk and suspect animals. Testing may also include an official genotype test, live-animal testing using a live-animal official test, the postmortem examination and testing of genetically susceptible animals in the flock that cannot be evaluated by a live animal test, postmortem examination of other animals, and postmortem examination and testing of animals found dead or cull animals at slaughter. Animals may not be tested for scrapie to establish the designation of the flock until they are test eligible. Animals are generally considered test eligible when the animals are over 14 months of age if born after the exposure or are 18 months post exposure. If testing these animals is necessary to establish the status of a flock they must be held for later testing unless sent directly to slaughter or a terminal feedlot.

(1) *Noncooperation.* If an owner does not make his or her animals available for testing within 60 days of notification by an APHIS or State representative, within 60 days of becoming test eligible, or as mutually agreed in writing by the Administrator and the owner, or fails to submit required postmortem samples, the flock will be designated a source, infected, or exposed flock, whichever definition applies and a noncompliant flock.

(2) *Notice to owner.* As soon as possible after making a designation or redesignation determination, a State or APHIS representative will attempt to notify the owner(s) of the flock(s) or animal(s) in writing of the designation.

(3) *Appeal.* The owner of an animal may appeal the designation of an animal as a scrapie-positive animal, high-risk animal, exposed animal, genetically susceptible exposed animal, genetically resistant exposed sheep, genetically less susceptible exposed sheep, low-risk exposed animal, or a suspect animal. The owner of a flock may appeal the designation of the flock as an exposed flock, an infected flock, a source flock, a flock under investigation, or a non-

compliant flock. The owner of a laboratory or test manufacturing facility may appeal the suspension or withdrawal of approval for a laboratory or a test. To do so, the owner must appeal by writing to the Administrator within 10 days after being informed of the reasons for the proposed action. The appeal must include all of the facts and reasons upon which the owner relies to show that the proposed action is incorrect or is not supported. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his or her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator. The action under appeal shall continue in effect pending the final determination of the Administrator, unless otherwise ordered by the Administrator. The final determination of the Administrator shall become effective upon oral or written notification, whichever is earlier, to the owner. In the event of oral notification, written confirmation shall be given as promptly as circumstances allow. The Administrator's final determination constitutes final agency action.

(Approved by the Office of Management and Budget under control number 0579-0101)

19. Section 79.5 is revised as follows:

§ 79.5 Issuance of Interstate Certificates of Veterinary Inspection (ICVI).

(a) ICVIs are required as specified by § 79.3 for certain interstate movements of sheep or goats and may be used to meet the requirements for entry into terminal feedlots. An ICVI and all copies must be legible and must show the following information, except when § 79.3 states that the information is not required for the specific type of interstate movement:

(1) The ICVI must show the species, breed or, if breed is unknown, the face color of sheep or the type of goats (milk, fiber, or meat), and class of animal, such as replacement ewe lambs, slaughter lambs or kids, cull ewes, club lambs, bred ewes, etc.; the number of animals

covered by the ICVI; the purpose for which the animals are to be moved; the address at which the animals were loaded for interstate movement or for movement to a terminal feedlot when an ICVI is required; the address to which the animals are destined; and the names of the consignor and the consignee and their addresses if different from the address at which the animals were loaded or the address to which the animals are destined; and if different the current owner;

(2) Each animal's official individual identification numbers: *Provided*, that, in the case of animals identified with official identifications devices or methods that include the flock identification number(s) assigned to the flock(s) of origin in the National Scrapie Database and an individual animal number unique within the flock, the flock identification number(s) may be recorded instead of the individual identification numbers, and for animals allowed by § 79.3 to move with group lot identification, the group lot number may be recorded instead of the individual identification numbers. An ICVI may not be issued for any animal that is not officially identified if official identification is required. If the animals are not required by the regulations to be officially identified, the ICVI must state the exemption that applies (e.g., sheep and goats moving for grazing without change of ownership). If the animals are required to be officially identified but the identification number is not required to be recorded on the ICVI, the ICVI must state that all animals to be moved under the ICVI are officially identified and state the exemption that applies (e.g. the ewes are identified with flock of origin tags so only the flock ID must be recorded on the ICVI); and

(3) A statement by the issuing accredited, State, or Federal veterinarian to the effect that on the date of issuance the animals were free of evidence of infectious or contagious disease and insofar as can be determined exposure thereto. This statement may be made with respect to scrapie for animals exposed to scrapie that's movement is not restricted that have been

designated genetically resistant or less susceptible sheep or low-risk exposed animals. Except as provided in paragraphs (b) and (c) of this section, all information required by this paragraph must be typed or legibly written on the ICVI. Note that in accordance with paragraphs (a), (b), and (e) of § 79.3, scrapie-positive, suspect, and high-risk animals, some exposed animals, and some animals that originated in an infected or source flock require permits rather than ICVIs.

(4) The ICVI must be signed by the issuing State, Federal, Tribal or accredited veterinarian and must be legible on all copies.

(b) As an alternative to typing or writing individual animal identification on an ICVI, if agreed to by the receiving State or Tribe, another document may be used to provide this information, but only under the following conditions:

(1) The document must be a State form or APHIS form that requires individual identification of animals or a printout of official identification numbers generated by computer or other means;

(2) A legible copy of the document must be stapled to the original and each copy of the ICVI;

(3) Each copy of the document must identify each animal to be moved with the ICVI, but any information pertaining to other animals, and any unused space on the document for recording animal identification, must be crossed out in ink; and

(4) The following information must be written in ink in the identification column on the original and each copy of the ICVI and must be circled or boxed, also in ink, so that no additional information can be added:

(i) The name of the document; and

(ii) Either the unique serial number on the document or, if the document is not imprinted with a serial number, both the name of the person who prepared the document and the date the document was signed.

(c) Ownership brands documents attached to ICVIs. As an alternative to typing or writing ownership brands on an ICVI, an official brand inspection certificate may be used to provide this information, but only under the following conditions:

(1) A legible copy of the official brand inspection certificate must be stapled to the original and each copy of the ICVI;

(2) Each copy of the official brand inspection certificate must show the ownership brand of each animal to be moved with the ICVI, but any other ownership brands, and any unused space for recording ownership brands, must be crossed out in ink; and

(3) The following information must be typed or written in ink in the official identification column on the original and each copy of the ICVI and must be circled or boxed, also in ink, so that no additional information can be added:

(i) The name of the attached document; and

(ii) Either the serial number on the official brand inspection certificate or, if the official brand inspection certificate is not imprinted with a serial number, both the name of the person who prepared the official brand inspection certificate and the date it was signed.

(d) If more than one page is used each page must be sequentially numbered with the page number and the total number of pages (for example 1 of 2, 2 of 2).

(Approved by the Office of Management and Budget under control numbers 0579-0101 and 0579-0469)

20. Section 79.6 is amended as follows:

a. In paragraph (a) introductory text by adding the words “, including scrapie surveillance activities,” after the words “control activities”;

b. By redesignating paragraphs (a)(10)(i) through (vi) as paragraphs (a)(12) through (a)(17), respectively, and by revising paragraph (a)(10);

c. By adding paragraph (a)(11);

d. In paragraph (b), by adding the words “from the date the State is notified of the deficiency” after the words “2-year extension”;

e. By adding paragraph (c); and

f. By adding an OMB citation at the end of the section.

The revision and additions read as follows:

§ 79.6 Standards for States to qualify as Consistent States.

(a) * * *

(10) Has effectively implemented ongoing scrapie surveillance that meets the following criteria:

(i) Collects and submits surveillance samples from targeted animals slaughtered in State-inspected establishments and from slaughter establishments within the State that are not covered under § 71.21 of this subchapter, or allows and facilitates the collection of such samples by USDA personnel or contractors; and

(ii) Transmits required submission and epidemiological information for all scrapie samples using the electronic submission system provided by APHIS for inclusion in the National Scrapie Database and for transmission of the submission information to an approved laboratory; and

(iii) Achieves the annual State-level scrapie surveillance minimums for sheep and goats originating from the State as determined annually by the Administrator with input from the States and made available to the public at <http://www.aphis.usda.gov/animal-health/scrapie> at least 6 months before the start of the collection period; or

(iv) Conducts annual surveillance at a level that will detect scrapie if it is present at a prevalence of 0.1 percent in the population of targeted animals originating in the State, with a 95 percent confidence.

(11) If a State does not meet the requirements of paragraph (a)(10) of this section as of [Insert date 30 days after date of publication in the Federal Register], the State must provide APHIS with a plan and a timeline for complying with all the requirements of paragraph (a)(10) by April 24, 2020, and must meet the requirements of paragraph (a)(10) of this section by April 26, 2021.

* * * * *

(c) When the Administrator determines that a State should be added to or removed from the list of Consistent States, APHIS will publish a notice in the *Federal Register* advising the public of the Administrator's determination, providing the reasons for that determination, and soliciting public comments. After considering any comments we receive, APHIS will publish a second notice either advising the public that the Administrator has decided to add or remove the State from the list of Consistent States or notifying the public that the Administrator has decided not to make any changes to the list of Consistent States, depending on the information presented in the comments.

(Approved by the Office of Management and Budget under control number 0579-0101)

Done in Washington, DC, this 15th day of March 2019.

Greg Ibach,

Under Secretary for Marketing and Regulatory Programs.

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